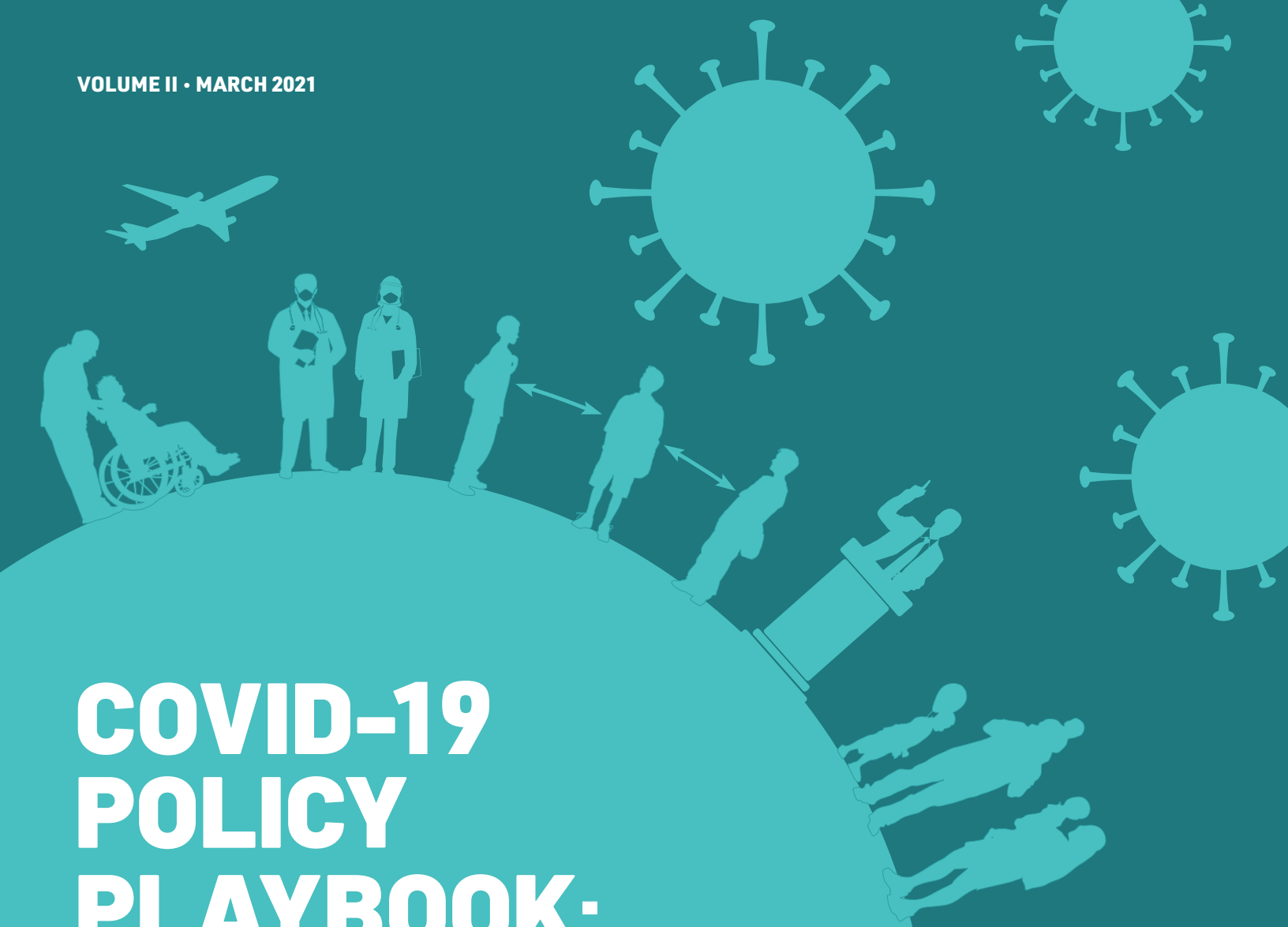
VOLUME II • MARCH 2021



COVID-19 POLICY PLAYBOOK:

Legal Recommendations for a Safer, More Equitable Future

Produced by Public Health Law Watch, an initiative of the George Consortium

In collaboration with:

Temple University Center for Public Health Law Research

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The Network for Public Health Law

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Acknowledgements

Support for this report was generously provided by the de Beaumont Foundation, the American Public Health Association, and the Robert Wood Johnson Foundation. The views expressed here are those of the authors.

The Editorial Committee would like to acknowledge the contributions of the following individuals: Faith Khalik (Northeastern University School of Law), Bethany Saxon (Temple University Center for Public Health Law Research), Liz Voyles (Brass Ring Communications), and Leslie Zellers (Public Health Policy & Law); and by research assistants Somer Brown, Olivia Melanson, and Sean Peters.

We also thank the following individuals who reviewed portions of the report: Luis Arteaga, Adam Crepelle, Sandro Galea, Daliah Heller, Claude Jacob, Howard Koh, Peter Lurie, Martha Katz, Matthew Pierce, Joshua Sharfstein, Sarah Somers, Silvia Yee, and Ruquaiijah Yearby.

Suggested citation:

Burris, S., de Guia, S., Gable, L., Levin, D.E., Parmet, W.E., Terry, N.P. (*Eds.*)(2021). COVID-19 Policy Playbook: Legal Recommendations for a Safer, More Equitable Future. Boston: Public Health Law Watch.

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Summary of Findings and Recommendations for Action

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This report, including 39 chapters by more than 50 experts, updates and expands the initial rapid COVID-19 legal assessment published in August 2020. The failures we noted in the first Report have only worsened, culminating in the sad moment in February when the country reached 500,000 deaths. For Volume II of the Report, our team has revisited the legal issues we first surveyed early in the pandemic, and have added new topics, including education, data systems, and the lessons of the 2020 pandemic election. Even for the subjects covered previously, this Report consists of largely new material, including new, post-election recommendations, which we highlight in this summary. Volume I confronted a historic failure of law and policy. Volume II points to a historic opportunity to remake our institutions, public and clinical health law and policy, and the social contract.

Once again, we have asked our authors to focus on how law has served the nation's response to COVID-19, and to offer concrete suggestions for immediate and long-term changes to better serve the health of the nation. Each of the six sections of the Report addresses a big question:

1. How can government power best be used to prevent and control pandemics like COVID-19?
2. How can law help best harness the power and overcome the limitations of a divided system of federal, state, and local governments?
3. What reforms are needed to get high quality, affordable health care to everyone during the pandemic and beyond?
4. What can law do to help ensure access to essential medicines and medical supplies?
5. What legal steps are needed to protect American workers and their families from COVID-19 and its economic side effects?
6. Finally, and most importantly, what must be done through law to knock down the structures of racism and inequality that produce health inequity now, and prevent the American people from working together for health and prosperity in the future?

In this summary, we synthesize the answers our authors have provided, including the most important next steps for getting control of COVID-19, and offer a blueprint for longer-term legal action to strengthen health and health equity in the years to come.

KEY FINDINGS FROM VOLUME I

In our first report last Summer, we offered three overall findings from the work of our authors:

> Decades of pandemic preparation focused too much on plans and laws on paper, and ignored the devastating effects of budget cuts and political interference on the operational readiness of our local, state, and national health agencies.
>
> Legal responses have failed to prevent racial and economic disparities in the pandemic's toll, and in some cases has aggravated them. COVID-19 has exposed too many empty promises of equal justice under law.
>
> Ample legal authority has not been properly used in practice — we've had a massive failure of executive leadership and implementation at the top and in many states and cities.

These same problems characterized the second six months of pandemic response. The full set of Volume I assessments and recommendations can be found at *COVID19PolicyPlaybook.org*.

Part I: How can government power best be used to prevent and control pandemics like COVID-19?

COVID-19 has proven beyond reasonable doubt that public health is truly public. It not only touches all of us, but it requires collective action through government to maintain and defend. In this pandemic, government in the United States struggled to do its public health duty, and law can and must play an essential role to get the enterprise back on track.

Controlling COVID-19

Government interventions in response to the COVID-19 pandemic have taken the form of an array of overlapping strategies to test for and track the spread of the disease; limit contact between people; mitigate infection risk when contact occurs through density and duration restrictions and the interposition of physical distance and

barriers; provide limited legal and economic supports for people, businesses, and institutions; and support the development and distribution of COVID-19 vaccines as they have become available. These efforts were inadequate to stop the United States from enduring the worst COVID-19 outbreak in the world. This is in large part because these layered strategies were pursued ad hoc at the state and local levels without consistency or coordination, adequate guidance or evaluation, or necessary information, in a contentious political atmosphere where the federal government consistently undermined public health efforts and messaging.

The Biden administration has already taken promising early steps to implement a coordinated national strategy. The administration has said it will use existing federal powers to advance COVID-19 responses, harmonize guidance to encourage good public health practices, promote vaccination, and collect necessary data—including data on racial, ethnic, and economic disparities—to clearly assess the areas where targeted interventions are needed. In all, it will prioritize equity in COVID-19 policies, including in vaccine distribution and the imposition of evidence-based community mitigation strategies and supports. Nevertheless, our federal system, which places primary reliance for public health on the states, means that inconsistencies and inattention to equity may remain as states go their own way

Several additional legal steps should be taken right away. State and local governments should continue to use targeted orders to implement social distancing and other community mitigation strategies when appropriate to reduce transmission of COVID-19 under guidance from the Centers for Disease Control and Prevention (CDC) about how to best target and layer these community mitigation strategies and standardize surveillance, contact tracing, and data management approaches. Congress should pass pending legislation containing economic and social supports and legal protections that allow people, businesses, and institutions to comply with community mitigation strategies and participate in COVID-19 surveillance, testing, and contact tracing initiatives, as well as support for equitable vaccine distribution and the safe reopening of schools. Additional resources and attention must be given to reduce racial and economic disparities in all of these initiatives.

Recommendations for a Safer, More Equitable Future

Successful use of government powers to respond to future pandemics and public health threats requires

1. a clear understanding of the scope of available public health powers;
2. a well-developed public health infrastructure;
3. a knowledge base that allows informed and equitable decisions to be made about public health;
4. policies that provide economic, social, and legal support to allow compliance with public health interventions and community mitigation strategies, and to mitigate disparate health outcomes; and
5. a centering of equity as a key priority across all of these efforts.

Most governments currently possess sufficient public health powers and emergency powers to respond to a variety of public health threats, but the use of these powers to address COVID-19 faltered in practice due to leadership and implementation failures. Future pandemic planning should study and account for these insights. Additionally, the ability of state and local officials to respond rapidly to emerging threats must be maintained in the face of misguided efforts by state legislatures to strip executive branch officials of public health powers and to further limit democratic participation in the electoral process. While states' experience with the pandemic should provide states with the impetus to review and reform their laws to ensure in the future a more effective, equitable and transparent response that adheres to constitutional limitations, legislatures should not crudely strip executive branch officials of the vital powers they may need to use in the next health emergency. Nor should they further limit democratic participation in the electoral process. Legislatures may need to more proactively define when public health interventions are required, and, ultimately, voters must impose accountability for leadership failure.

Public health infrastructure should also be bolstered. The COVID-19 pandemic has demonstrated the importance of public health capacity, and Congress should fund efforts to expand the public health workforce and modernize and expand public health institutions. The federal government should substantially strengthen its long-term support for legal epidemiology — scientific research on the health effects of law and legal practices — beginning with the impact of law on the COVID-19 response. If we better understand the role of law as a determinant of health, it will allow us to craft better interventions.

Planning and implementing effective and equitable interventions requires adequate information. The federal government should centralize, coordinate, standardize, and regulate data collection and distribution related to public health responses, including the use of a consistent approach for contact tracing. The data systems required need drastic upgrading and harmonizing at the local, state, and federal levels. Work to improve our national health data infrastructure depends on creating new rules that create safe but usable health information systems: the law must protect privacy and data security, prevent discrimination and disparate impacts, and promote transparency, accuracy, and accountability — but it must also ensure that data can be readily used for important public purposes.

Federal, state, and local governments should enact policies that support individuals, businesses, and institutions during pandemics. Measures such as economic supports (i.e., direct payments, child care support, unemployment extensions, rental and food assistance) and legal protections (i.e., foreclosure, eviction, and utility shutoff moratoria, employment and anti-discrimination protections, and workplace safety and leave policies) allow for better adherence with public health interventions and community mitigation strategies and can help to mitigate disparate health outcomes. These policies foster the more resilient and equitable society that we should be striving for.

The COVID-19 pandemic revealed starkly how pernicious structural and societal factors like racial and ethnic health disparities and

economic precarity place racial and ethnic minorities, people who are low income, and people with disabilities at greater health risk. It is essential that public health policies — in conjunction with broader social policies that affect health outcomes — prioritize equity.

Part II: How can law help best harness the power and overcome the limitations of a divided system of federal, state, and local governments?

In the United States, power is divided among the federal government and the states and Tribal authorities, among branches of government within each jurisdiction, and among states and their local governments and Tribal authorities. This can be a strength. During the COVID-19 pandemic, this dispersion of power has made it possible for some levels of government to respond to the pandemic even when others failed to do so — but it also enabled political leaders to try to evade responsibility, and facilitated an inconsistent and often incoherent response.

Controlling COVID-19

The good news is that the Biden administration has taken a more proactive stance. It has made COVID-19 a priority. It has been holding regular pandemic briefings by scientists, coordinating action with states and cities, emphasizing equity, and focusing on vaccine distribution and Congressional passage of a significant relief package to support vaccine distribution and mitigate the economic fallout of the pandemic. The Biden administration has also installed new leadership at CDC, and has vowed to let science guide that agency. That promise must be kept, as CDC guidance on a range of issues that will arise in the coming months will be critical to ending the pandemic. State leaders must attend to CDC advice, and be transparent about the criteria they apply as they maintain or ease emergency measures during the remaining months of the pandemic. Equity must be a central feature of all decision-making. States should also avoid preempting local public health measures, and respect Tribal authority.

Recommendations for a Safer, More Equitable Future

As we move past COVID-19, it is essential that Congress does not repeat the mistake of neglecting pandemic preparedness in the years between pandemics. In Volume I, we concluded that the national lack of readiness for COVID-19 was not a matter of bad laws or plans on paper, but rather neglect of the human and administrative infrastructure that is needed to put those plans into practice when the emergency comes. Congress should appropriate the necessary funds to replenish the Strategic National Stockpile (SNS) and revise the Public Health Services Act, as necessary, to mandate that the SNS be replenished after any use. CDC should also revise its quarantine regulations to provide transparency in the criteria it will use when using its authority in the years to come. The federal government must also fulfill its support obligations to Tribal authorities, and appropriate sufficient funds to ensure safe drinking water and broadband for all who live under Tribal authority. Equity needs to be a lodestar for all executive branch actions.

Congress should also act to ensure that in the next health crisis, federal scientific guidance for states, cities, and the public is not subject to undue political interference. This includes re-examining the legal status and organization of our key health agencies, CDC and Food and Drug Administration (FDA), to ensure independence from political pressure. It could include creating an independent federal expert agency whose function is to produce clear and reliable public health guidance for both the public and policy makers. Congress should consider whether the leadership of key health agencies should be required to have specific expertise, and should be removable only for cause.

States cannot play their vital roles in public health without their own strong public health infrastructure. Like Congress, state legislatures need to appropriate sufficient funds going forward to ensure that health departments can effectively perform their disease detection and control work. States should consider amending their constitutions to permit deficit-spending during public health emergencies so that their capacity to respond and mitigate the impact on vulnerable populations is not totally reliant on the federal government.

During COVID-19, we have seen cities where leadership and the public wanted measures that were different from those imposed by the state. Such policy diversity within states has many benefits. Local governments can use health authority to develop health measures tailored to the needs and preferences of the community. States should reject new efforts to restrict the authority of local governments to take steps to enhance equity, and empower governors during a health emergency to suspend laws that preempt effective and equitable local responses. States should also repeal laws that penalize local officials who enact or enforce potentially preempted laws, and work with and respect Tribal jurisdictions.

Part III: What reforms are needed to get high quality, affordable health care to everyone during the pandemic and beyond?

COVID-19 descended on a health care system that was critically unprepared for such a widespread and deadly virus. It was a system that was already underperforming across multiple dimensions: access, financing, delivery, and the integration of technology. It was also a system under sustained political and regulatory attack by the Trump administration, which continued to push policies intended to weaken and even destroy the Affordable Care Act (ACA). Fragmented models of care and data flow are problematic at the best of times. In a pandemic they are a recipe for the disaster we observed. However, COVID-19 found one more way to twist the knife. The pandemic's negative impacts on the economy, some temporary, many more likely permanent, led to widespread unemployment. Suddenly, the core organizing principle of U.S. health care financing — employment-based health insurance — was swept away, jeopardizing access to health care for millions as the safety net predictably also underperformed.

Controlling COVID-19

Some urgent issues have already been addressed by executive orders issued by President Biden. These include opening a special enrollment period on the federal marketplace and critically reviewing regulations and policies of the prior administration that had the effect of weakening provisions in the ACA. Other

recommendations, such as increasing eligibility for marketplace policies, increasing subsidies, and capping premiums, should be legislative priorities. Other urgent tasks should include increasing the Medicaid Federal Medical Assistance Percentages (FMAP) formula for states to 90% for all program costs for the duration of the emergency and recovery period. The Department of Health and Human Services (HHS) should stop defending waiver approvals involving work requirements in the lawsuits before the Supreme Court and elsewhere, and revise its Section 1115 waiver policy to encourage the expansion of coverage. The increase in telehealth services during the pandemic should continue and be improved; first by reimbursing community health workers who train and educate those with health disparities; second by providing technology and broadband subsidies for high utilizers of Medicare and Medicaid programs. While the Biden administration completes its review of the punitive changes made by the previous administration to the Title X family planning program, it should move swiftly to allow medication abortion drugs (mifepristone) to be ordered through mail-order prescription services and retrieved at retail pharmacies. Meanwhile states should cease abortion exceptionalism whereby reproductive health services are not categorized as essential services.

Recommendations for a Safer, More Equitable Future

The Patient Protection and Affordable Care Enhancement Act (H.R.1425), passed by the House of Representatives in 2020, provides a roadmap for reversing the last administration's attacks on the ACA. However, the Biden administration will need to go further than reversing prior policies, incentivizing the 12 hold-out states to expand Medicaid, making marketplace plans affordable for more people, and continuing the telehealth revolution. Health care costs incurred by individuals and states create structural barriers to care requiring major legislative reform, such as the introduction of a "public option." Priority should also be given to designing a universal insurance coverage mechanism to ensure access to coverage during a declared public health emergency.

COVID-19 has framed and highlighted many legal and policy flaws that had been ignored for decades. Notwithstanding mental health parity legislation, federal and state governments have failed to adequately promote mental health education or strengthen the safety net to provide care and treatment. Equally, treatment of opioid use disorders must be normalized by removing the extraordinary and unnecessary limits on prescribing buprenorphine and agonists, and restrictive telemedicine rules. Residents of long-term care facilities were suffering before the pandemic, and the defects of that care system have been magnified by COVID-19; stronger regulation of staffing and infection control and enforcement are overdue.

Finally, building resilience against future public health emergencies such as substance use epidemics and viral pandemics, requires a commitment to health equity. Equity depends not merely on universal access to care or fighting implicit bias in its delivery but removing disparities in health caused by social determinants such as education, income, and social inclusion.

Part IV: What can law do to help ensure access to essential medicines and medical supplies?

COVID-19 revealed a federal government unprepared to manage the fundamentally practical task of ensuring access to essential medical supplies and personal protection. An essential bureaucratic infrastructure of data and expertise on supply chains and coordinated purchasing was simply missing. In the last six months, the federal government has taken some important steps — like acting to increase production of glass vials for vaccines — but shortages persist, and coordinated national production and distribution remains, at best, an aspiration. In the domain of medicines and vaccines, poor vetting of COVID-19 tests, and ill-advised emergency approvals for hydroxychloroquine and chloroquine raised fears about FDA independence and reliability. The agency redeemed itself with its management of emergency vaccine approvals, but the experience has raised important questions of legal reform in the agency's structure and rules. In the long run, only good government management, supported by sustained funding, can maintain a supply system that can withstand pandemic shocks.

Controlling COVID-19

Intelligent, data-driven management of supply chains is crucial to prevent and alleviate shortfalls. The federal government should rebuild staff and use its manifold legal authority to require transparency from manufacturers all along the supply chain, and should use new and existing data sources to make sure that personal protective equipment (PPE), medicines and vaccines are being distributed fairly and in line with law and public priorities. This includes the federal government immediately and substantially increasing the SNS of traditional and alternative PPE — as it has done for COVID-19 treatments and vaccines — while developing an equitable national strategy for distribution to states.

Rapid and transparent regulatory action is essential to support innovation and keep junk out of the market, but it must be carried out in a way that respects scientific requirements and maintains public trust. The pandemic has challenged FDA in all sorts of ways: with tests, masks and other PPE, it had to uphold quality standards and fight counterfeiting, in the face of great demand and a proliferation of new providers. FDA, the National Institute for Occupational Safety and Health (NIOSH), and the Occupational Safety and Health Administration (OSHA) should finalize all draft COVID-19 guidance documents and standards for respirators, imported masks, and testing newly fabricated PPE. Federal agency civil rights offices should develop, expand, or update best practices and guidance for the allocation of scarce resources and crisis standards of care consistent with federal antidiscrimination laws. With drugs and vaccines, FDA has had to manage the tension between getting a vaccine on the market, determining with reasonable confidence that the candidates were both effective and safe, and doing so with a transparency and scientific rigor that would reassure the public that vaccination was in their best interest. There are continued challenges ahead: Expanded Use Authorizations (EUA) before the full required sequence of clinical trials is complete makes it difficult if not impossible to enroll

participants to complete the trials leading, for example, to a lack of trial evidence of the effect of the vaccines on transmission.

Immediate and substantial federal funding and technical support is vital for states, cities and businesses struggling to ensure equitable access to PPE, medicines and vaccines. Congress should increase and maintain funding for public health emergency preparedness through a dedicated public health emergency fund; should expand support for the National Hospital Preparedness Program, the SNS, and vaccine manufacturing capacity; and should fund state, local, and private sector efforts to expand COVID-19 vaccination capacity.

Recommendations for a Safer, More Equitable Future

In the domain of essential supplies, medicines, and vaccines, preparedness requires ongoing robust support of human and material infrastructure in the years and decades to come. In a better future, the nation will not be shocked to learn that pandemics can stress supply chains while prompting dramatic spikes in demand. To get there, the federal government must permanently strengthen the SNS and its supply chain management capacity. Congress should reaffirm the role of the SNS as the primary resource for the nation during emergency surges in demand, and institute a long-term funding plan for assuring supplies commensurate with predicted need. It should fund, and the Department of Health and Human Services (HHS) should properly implement and manage, the long-term staff and infrastructure to monitor, track, and use the resources of the Biomedical Advanced Research and Development Agency (BARDA) to proactively address deficiencies in the supply chain for essential medical equipment. HHS should develop, with real attention, new regulations on emergency supply chain management including developing and implementing "stress tests" for supply chains for key products.

2021 will also be the year to start building on COVID-era innovations to develop and institutionalize methods of rapid response production. In years past, BARDA supported new technologies and manufacturing ideas, but failed to get innovation into infrastructure and practice. That is a correctable mistake. The end of the acute COVID-19 pandemic should also mark the start of serious legal reconsideration of FDA's independence, its regulatory approach to PPE, and the nature and role of EUAs for vaccines and medicines during a pandemic emergency.

The problems of equitable access to medical supplies, medicines, and vaccines is yet another reason for states and local governments to reinvest in their public health infrastructure. As with the federal government, the time to build human and institutional capacity to manage PPE and vaccine distribution during an emergency is before the emergency. State legislatures or executive agencies should also develop and approve protocols for crisis standards of care and allocation of scarce medical resources and services during declared emergencies, disasters, or public health emergencies. They should also set clear indicators and triggers for when crisis standards of care apply, including guidance for the distribution of new treatments and vaccines for COVID-19 that center both efficacy and equity.

Part V: What legal steps are needed to protect American workers and their families from COVID-19 and its economic side effects?

A pandemic meets its hosts as it finds them. In a nation where inadequate protection for workers and families is the status quo, COVID-19 has put them, and disproportionately those who are people of color, at greater risk from the loss of income, housing and food security; workplace injury and infection; and the ramifications of school shutdowns. This reality, in addition to the lack of adequate contingency planning and safeguards for an extended public health emergency have left the nation's residents more vulnerable to the virus.

Controlling COVID-19

To protect the health of families and workers, federal and state governments must increase and extend supports for education, housing, and food security. Expanding vaccine access to teachers as rapidly as possible — as the Biden administration is trying to do — will clear some of the roadblocks, but clear guidance and additional funding is required to open schools safely. It remains vital to address the needs of children normally met when they are in school – access to healthy meals, broadband, special education and safe supervision. Families must receive the necessary protections to stay in their homes — eviction and foreclosure moratoriums should be extended, and additional federal loans and rental assistance provided for property owners and tenants. Housing must be created and maintained for people living in poverty, and supportive housing should be established for people experiencing homelessness. The emergency 15% increase to the maximum Supplemental Nutrition Assistance Program (SNAP) benefits and the able-bodied adults without dependents (ABAWDs) waiver should be extended and linked to economic recovery.

COVID-19 has exposed and heightened the need for policies that enable workers to survive financially and care for themselves and their families during a crisis. Paid sick leave and unemployment insurance provide lifesaving support for impacted workers. However, millions of workers were left out from paid leave requirements with low-wage workers and workers of color more likely to be excluded. Congress should pass President Biden's proposal to reinstate and expand the right to emergency job-protected leave, and the Department of Labor should enforce paid leave protections. Although the omnibus and relief package passed by Congress in December 2020 provided relief for workers by extending regular unemployment benefits through periods of high unemployment, implementation barriers have continued and have aggravated inequities suffered by women and people of color.

Workers who have provided essential services have been hailed as heroes, but many have not been afforded the basic protections to safeguard them from workplace infections and death. Access to vaccines is imperative, but just one need. Recommendations for needed protection include enactment and enforcement of workplace safety laws, including airborne infectious diseases requirements at the state and national level; a national worker COVID-19 protection plan; enforcement of existing OSHA protections, including mandated testing and disclosure of de-identified testing information and aggressive use of the

Defense Production Act to obtain PPE. Calls for broader immunity shields for employers who put workers in harm's way should be resisted, especially where the conduct to be shielded actually increased transmission.

Recommendations for a Safer, More Equitable Future

This nation must acknowledge that before the pandemic, existing programs did not sufficiently protect workers and families from challenges to their jobs, income, housing, and food security, and that gaps in protections disproportionately impact people on low incomes and people of color. These failings left us more vulnerable to the virus. To meet future challenges to the public's health as a stronger, more resilient nation, workers and families need stronger social supports built into the law.

Legal support for workers starts with safety on the job. COVID-19 has demonstrated a compelling need to enact a national workplace safety law, as well as permanent structural paid leave reform to ensure universal, equitable, inclusive, comprehensive paid sick days, paid family and medical leave for all workers, and an updated, well-implemented unemployment insurance system.

Law must also do a better job ensuring housing quality and security. The inequities of COVID-19 call out for measures to redress the inadequate housing supply and health-harming housing conditions, and to provide rental subsidies and eviction protections. Issues that lead to unstable housing and homelessness, including access to mental health and substance use disorder services must be addressed in an effort to end the cycle of poverty and unstable housing. SNAP benefits should provide families with basic food security, calibrated to economic indicators; the ban on SNAP participation by individuals with felony drug convictions should be repealed.

Equitable access to broadband for all families is needed, but particularly to ensure that children of color as well those who are geographically isolated or live in lower resourced households are able to attend school remotely. Contingency planning needs to be in place for children who rely on essential economic and safety supports provided by their schools.

Finally, future emergency preparedness planning must include a focus on responses necessary to mitigate the economic fallout and instability from an extended civic or public health emergency accompanied by business and school shutdowns. Enhanced protections for workers and families will yield a more equitable and stronger society, and a nation better prepared for future challenges to the nation's health and safety.

Part VI: What must be done through law to knock down the structures of racism and inequality that produce health inequity now, and prevent the American people from working together for health and prosperity in the future?

COVID-19 exposed the ways in which U.S. systemic inequities have created disparate and inequitable health outcomes. It showed how deeply racism and discrimination are entrenched in our laws and policies. Many, including people with disabilities, immigrants, Black, Indigenous, and other people of color, people who are incarcerated, and LGBTQ communities, are among those who have faced the greatest challenges as a result of COVID-19. This section of the report identifies short- and long-term legal and policy solutions to ensure that those who have already suffered the most will not continue to pay the heaviest price of the COVID-19 pandemic.

Controlling COVID-19

Accurate data documenting disparities is a starting point for change. The inability to identify hot spots, track community infection and death rates, and disaggregate data based on socio-economic factors has left us with gaping holes in our ability to respond. Across every level of government, investments to standardize data collection and analysis must be prioritized to accurately address community needs and pinpoint those experiencing the greatest health risks.

Federal agencies must take proactive steps to clarify legal protections for the communities experiencing health and social inequities. The guidance should be targeted to local and state governments and private entities, and cover topics such as the Religious Freedom Restoration Act; Section 1557 of the Affordable Care Act; sex discrimination prohibitions in public accommodations; requirements under the Americans with Disabilities Act; and the Rehabilitation Act. Government agencies should reverse or withdraw steps taken by the previous federal administration that promoted exclusion and discrimination.

Federal agencies must take steps to remove funding exclusions and unnecessary limits on programs to ensure all communities are able to access critical life supports and basic services. For example, prohibitions on the use of Medicare and Medicaid funds in correctional facilities should be removed. The exclusion of undocumented individuals from pandemic economic relief and other critical services must be eliminated, and the last administration's more onerous definition of public charge should be reversed. State governments should leverage their authority and discretion over the use of federal, state, and local funding to provide safe spaces for at-risk communities, funding to community-based organizations, and to expand health and social services.

Finally, state and federal governments should develop and implement policies to address the coronavirus's spread in all detention facilities, including immigration facilities. ICE should cease all immigration raids and deportations that are not public safety concerns. The Biden administration must also ensure that all the communities addressed in this section are able to access vaccines quickly and equitably, including people who are detained or who are unable to leave their home due to a disability.

Recommendations for a Safer, More Equitable Future

The new federal administration has already taken action through executive orders on immigration policy, racial equity, the justice system, and LGBTQ data and discrimination protections, which are all important first steps. As governments at all levels build

upon these efforts, they must aggressively address structural discrimination and racism. The legal experts writing in this report identified ongoing exclusionary and discriminatory practices and policies that have left communities more vulnerable to the pandemic, and likely to be without critical services to recover.

We must consider more comprehensive policy making approaches to civil rights, immigration, and incarceration. Policy approaches must eliminate structural barriers to good health by, for example, eliminating the exclusion of immigrants from public benefits and offering a way to citizenship, stopping practices that result in the excessive incarceration in Black, Indigenous and other communities of color, and successfully secure reentry for those leaving facilities.

COVID-19 demonstrated how communities experience the effects of a public health emergency in different ways, suggesting that ameliorative policies may not work across the board. All levels of government should consider "targeted universalism," and develop guidance on this approach to ensure that policies, responses, and resources benefit all populations while addressing the unevenness of social, racial, and health inequities.

While our country is grappling with a pandemic, large swaths of our country are also in a war against facts, still believing that the pandemic is a hoax and that our government is untrustworthy. These beliefs are part of a broader misunderstanding of our nation's history of structural discrimination and racism. As Harris and Pamukcu state in their Chapter: "The absence of a shared infrastructure of facts including a recognition of structural racism threatens our health, our social fabric, and the very mechanisms of our democracy." Our country will not achieve a successful collective approach to address this and future pandemics if we do not face the facts together. Local and state governments should support truth and reconciliation committees to help confront structural racism and discrimination in laws and policies, and identify new resource distribution efforts using the targeted universalism approach.

Another way to address the mistrust and lack of connection between government and communities is through innovative partnerships. The pandemic has shown us that no agency, or even the government as a whole, can address the severity of its impact on its own. Throughout the past year, community organizations have stepped in to fill the gaps, including creating safe spaces for mental health, distributing resources including food and PPE, and helping to dispel myths. By leveraging existing infrastructure and partnerships with public health officials, social justice movements, and community leaders, government efforts will be more successful. These efforts can also help to spur economic growth and stability, bring community expertise to policy planning, and inform recovery efforts.

We have the opportunity to dismantle unjust and inhumane laws and policies and to help heal a nation from this pandemic as well as our legacies of racism, segregation, and discrimination. It is imperative that policy makers not only look at short-term solutions to address the impacts of COVID-19 but to seize this opportunity to enact greater, more comprehensive reforms that will address unjust and unnecessary discrimination and exclusion resulting in health inequities.

EQUITY AS A PRIMARY CONCERN OF THIS ASSESSMENT

Law and policy play an important role in limiting or exacerbating health disparities and health inequities. Health disparities are differences in health outcomes that people of different demographic backgrounds experience. Health disparities were all too common in the United States before COVID-19, and have been striking during the pandemic. As Patricia Williams points out in her powerful closing reflections on this Report, these disparities do not arise from bad individual choices or biological differences between races but the social factors that shape people's lives every day "in the ghettoized geographies that have become such petri dishes of contagion." These disparities are not inevitable. We as a society have created them. Centuries of oppression through policies, norms, and institutional practices shape individual experience and over time have created the inequitable society we inhabit. Laws and policies too often reinforce health inequities by making resources scarce for many or creating unhealthy environments, especially in poor communities and communities of color. But the tools of law and policy can also be the deliberate intervention to change the fundamental drivers of inequity and increase health equity.

A Social Contract for Solidarity and Equity

We finish with a return to the most basic "legal" questions: What are the terms of the social contract in this country? What can each of us expect from the other, and from our government?

The national and state constitutions define the powers of government and their separation, and provide protection for individual rights. On a deeper level, though, they — and the landmark court decisions that interpret them — define the fundamental nature of our civil society, articulating core values and providing the ultimate blueprint for how we cooperate and coexist. COVID-19 is just one in a series of events that has tested the social union. Public health as a practice, and as a branch of law, has a lot to say about our society's values and aspirations.

Jacobson v. Massachusetts, the defining case that has endured for more than a century of public health, built its analysis on the nature of the American social contract. In 1902 in Massachusetts, the Board of Health of Cambridge ordered all residents to be vaccinated. Henning Jacobson, a local minister, refused and was fined $5. Backed by anti-vax advocates, he took his case all the way to the Supreme Court. The Court explained why Mr. Jacobson could not claim a right to opt out. He did indeed have a constitutional right to liberty, but if it came down to a conflict between his individual liberty and the welfare of the community, well — as the old maxim put it in other cases — *salus populi suprema lex*: the health of the people is the supreme law. To the Supreme Court, it was "a fundamental principle of the social compact that the whole

people covenants with each citizen, and each citizen with the whole people, that all shall be governed by certain laws for 'the common good,' and that government is instituted 'for the common good, for the protection, safety, prosperity, and happiness of the people, and not for the profit, honor, or private interests of any one man, family, or class of men.'" We Americans get all the benefit of civil society — cooperation, good government, potable water, education, public health protection, democracy, and even liberty itself. In return we agree that there may be times when our individual interests must give way to the needs of society. That is a principle of social solidarity, the idea — indispensable for a functioning democracy — that we are all in this together, sharing the sacrifices as well as the benefits of community.

Solidarity has a twin, the equally indispensable principle of social equity. We are not only all in this thing together, but we are all entitled to the same inalienable rights that make us equal in status, equal in opportunity, and entitled to fairness in outcomes. For far too long, all Americans have not been truly equal in their social or legal status, opportunities have been created much more for some than others, and the outcome has been historically high levels of economic and social inequality. Law and policy play an important role in limiting and in exacerbating these inequities and the health disparities that result. The analyses and recommendations in this Report have been guided by an equity framework and have endeavored to name specific legal and policy steps that can improve equity in the COVID-19 response and beyond.

A positive vision of the possibilities of public health (law) is indispensable if we are to rise from the ashes of failure. Equity and solidarity are the necessary values to guide a collective effort to make sure that health — including safety from the next pandemic — does not depend for Americans on their race, ethnicity, income, or ZIP code. This country can heal itself from COVID-19, move on from 2020's historic failure, grasp the historic opportunity for reform and renewal, and thereby ready itself for a better response to the next pandemic. And, as we concluded in our first Report, we should settle for nothing less.

RECOMMENDATIONS ADDRESSED BY CONGRESS AND THE BIDEN-HARRIS ADMINISTRATION

Prior to the August 2020 publication of Volume I of this assessment, Congress had passed two major pieces of COVID-19 relief legislation. Legal issues raised or answered by those laws, the Coronavirus Aid, Relief, and Economic Security (CARES) Act (on March 17, 2020) and the Families First Coronavirus Response Act (FFCRA) (on March 18, 2020), featured in many of our recommendations. Thereafter, much anticipated further legislation failed to materialize until after the November 2020 election. On December 27, 2020, President Trump signed new relief legislation as part of the Bipartisan-Bicameral Omnibus COVID Relief Deal (Dec. 27, 2020). That relief package was primarily financial, consisting of payments to individuals, supplemental jobless benefits, help for small businesses and a moratorium on evictions.

The inauguration of President Biden presaged a rapid ramp-up in ameliorative provisions, many of which mirror or at least anticipate recommendations made by our authors in both volumes of the assessment.

By early March 2021, President Biden had signed 35 Executive Orders (EOs). Some, such as EOs directed at securing the public health supply chain or opening a special enrollment period for federally facilitated individual health insurance plans, were immediate reflections of experts' assessments. Other EOs suggest that additional important reforms will be coming after study or administrative process. These include public health data management, health equity, and combating discrimination on the basis of gender identity or sexual orientation. Separately, by letter, the Biden Department of Justice (DOJ) notified the Supreme Court that the new administration disagreed with the arguments previously made that the Affordable Care Act (ACA) was unconstitutional. Similarly, the DOJ notified courts that it would no longer defend the Trump administration's "public charge" regulation and the new Homeland Security Secretary Alejandro Mayorkas announced the end of its implementation.

President Biden's first signature legislation was The American Rescue Plan Act (ARPA) (on March 11, 2021). Legislative provisions that touched the recommendations made in the two volumes of our assessment include:

- Major additional funding of the safety-net with additional funds aimed at reducing child poverty through a fully refundable tax credit in addition to extending FFCRA and CARES stimulus checks, unemployment support, SNAP supplementation, rental assistance, and food support together with additional rental and utilities assistance.
- Supporting the workforce with emergency federal aid for federal workers, increased funding for OSHA activities involving high-risk workplaces, and funds to help reopen schools and support childcare.
- Employees who lose jobs or benefits qualify for 100% COBRA health-insurance subsidies.
- Major changes to the eligibility for and amount of subsidies (tax credits) available to purchasers of individual health insurance (through the ACA marketplace), including eliminating the annual income cap and limiting the amount households pay to 8.5% of annual income.
- COVID-19 vaccines and treatment are covered without cost sharing by Medicaid and CHIP at 100% of the Federal Medical Assistance Percentage (FMAP) until one year after the end of the Public Health Emergency. States have the option of extending this to uninsured persons.
- Temporary increases to the state base FMAP to encourage non-expansion states, such as Florida and Texas, to expand Medicaid.
- Increases in funding for mental health and substance use disorders.
- Funding for Defense Production Act (DPA) activities such as manufacturing and procuring PPE and vaccines.
- Decreasing inequities with funds for rural health care, indigenous persons, and disadvantaged (particularly Black) farmers.

Most of these provisions are time-limited and, as a result, several of our recommendations in Volume II are that they be made permanent.

Top Recommendations for Action

The recommendations here have been distilled by the Editorial Committee from hundreds of specific legal ideas offered by Chapter authors. For more details and explanations, see the individual chapters noted with each recommendation.

Strengthening the Public Health System

- Congress and the White House should jointly convene an independent commission or task force to investigate the preparation for, the response to, and the inequities exacerbated by COVID-19 (see Anderson & Burris, Medical Supplies; Jacobson et al., Executive Decision Making; Harris & Pamukcu, Civil Rights).
- Policymakers should consider providing greater structural independence to the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA), or creating a new health information agency, to insulate public health guidance and regulatory actions from political interference (see Wiley, Federalism, Volume 1; Robertson & Salwa, Independent Agency).
- Congress should designate a single federal agency or data trust to standardize collection and publication of rich data illuminating health and health equity, create a modern national data information infrastructure, and ensure privacy and publicly beneficial use (see Fowler et al., Data Collection).
- State legislatures should enact laws that provide substantive standards to guide executive officials during public health emergencies, without reducing the scope of public health powers (see Gable, Movement Restrictions).
- Congress should reaffirm and make mandatory the role of the Strategic National Stockpile (SNS) as the primary resource for supplies required during emergency surges in demand, and institute a long-term funding plan for assuring supplies commensurate with predicted need (see Anderson & Burris, Medical Supplies; Wiley, Federalism).
- The federal government should fulfill its treaty and trust obligations to Tribes, and both the federal government and the states should support Tribal public health, including through ensuring the provision of clean water, safe housing, broadband, access to health care, and data access (see Tanana & Hoss, Tribal).
- Local governments should recognize and address racism as an institutional and systemic issue, such as by declaring racism as a public health crisis (see Harris & Pamukcu, Civil Rights).
- The Health and Human Services Office for Civil Rights should develop, expand, and update best practices and guidance for the allocation of scarce resources and crisis standards of care consistent with federal antidiscrimination laws (see Gable, Allocating Medical Resources).
- Public health officials at all levels of government should make equity a central focus of pandemic response, and work to reduce the inequitable impact of public health emergencies (Jacobson, et al., Executive Decision Making).
- The Food and Drug Administration should comprehensively assess its procedures, standards, and practices for Emergency Use Authorizations (EUAs) (see Zettler et al., Vaccines).

Protecting Communities, Workers, and Families

- Congress and states should enact strong workplace safety laws requiring airborne infectious disease protections; Occupational Safety and Health Administration (OSHA) and state OSHA plans should mandate necessary disease testing and public disease data reporting (see Yearby, Worker Protection).
- Congress should move to eliminate food insecurity in the US through significant long-term enhancements to the SNAP program (see Swinburne, Food Insecurity).
- Congress, state legislatures, and local governments should adopt and enforce paid leave to ensure universal, equitable, inclusive, and comprehensive paid sick days and paid family and medical leave for workers (see Terman & Evermore, Paid Sick Leave).
- Congress and the states should comprehensively rebuild the benefit and technology structure of the unemployment compensation system to assure all workers have access to sufficient and timely benefits, and should eliminate taxation of unemployment benefits (see Terman & Evermore, Paid Sick Leave).
- Congress should enact comprehensive immigration reform that provides undocumented immigrants with a pathway to citizenship and reduces immigration insecurity (see Parmet, Immigration).
- Congress should amend the Affordable Housing Credit Improvement Act of 2019 to increase the tax credit allocations by 50% to increase the supply of affordable housing (see Anderson, Housing).
- States should repeal and reject efforts to restrict local authority to adopt health and equity promoting local laws (see Haddow et al. Preemption).
- Congress and state legislatures should comprehensively reform current laws governing evictions, mortgage foreclosures, and utility shut-offs to end inhumane and socially costly housing insecurity (see Anderson, Housing).

- Public housing authorities should take all measures to protect tenants from loss of housing, and local governments should provide supportive housing for people experiencing homelessness (see Anderson, Housing).
- Legislators should require prisons and jails to implement policies to address COVID-19 behind bars, and to frequently report data on infections, deaths, and releases that include demographics (see Beletsky & Bresler, Criminal Justice).
- Congress should act to promote greater competition in broadband, expand subsidies to ensure equitable access, and bar states from prohibiting local broadband initiatives (see Lawton, Broadband).
- States should develop plans to maintain and prioritize in-person education safely during public health emergencies (see Kershner & Silverthorn, Children).
- States should stop practices like pre-trial detention and cash bail, and decriminalize "quality of life" offenses (see Beletsky & Bresler, Criminal Justice).

Enhance Quality and Accessibility of Health Care

- Congress should make permanent provisions in the American Rescue Plan Act relating to subsidies to the ACA marketplace, Medicaid coverage reforms, and expansion of Medicaid and CHIP eligibility (see Huberfeld & Watson, Medicaid; Weeks, Private Insurance; Rosenbaum & Handley, Uninsured).
- States should follow the lead of the federal government and open special enrollment periods and extend their end-dates for all state-operated marketplaces (see Weeks, Private Insurance).
- States should enact individual health insurance mandates and provide for a "public option," publicly funded health insurance to stabilize markets and reduce costs (see Weeks, Private Insurance).
- CMS should withdraw its guidelines favoring using Section 1115 waivers to impose work requirements and block grants and deny renewals of same and publish new policies encouraging the expansion of Medicaid coverage (see Huberfeld & Watson, Medicaid).
- Congress should enhance funding for nursing homes, and the federal government and states should strengthen nursing home regulation and enforcement (see Sklar, Long-Term Care).
- Congress and state legislatures should decrease barriers to accessing OUD treatments, including buprenorphine and methadone (see Davis & Lieberman, Opioid Use Disorder).
- Congress and state legislatures should comprehensively remove regulatory, financial, and technological barriers to the use of telehealth to deliver health, mental health, abortion and substance use disorder treatment services (see Schmit, Telehealth; Rebouche, Abortion; Davis & Lieberman, Opioid Use Disorder; Krueger, Mental Health).

Preserving Democracy in Pandemics and Beyond

- Congress should set national minimum standards and provide adequate funding to protect election administration in voting during health and other emergencies (see Hunter, Elections).
- States should maintain and expand voting options that protect the right to vote during health and other emergencies (see Hunter, Elections).

Introduction: Politics, Policies, Laws, and Health in a Time of COVID-19

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Has there ever been a more important time to consider how politics, policies, and laws influence health? We are, as a country, in the midst of unprecedented turmoil, all of which has implications for our health. The COVID-19 pandemic is the most obvious clear and present danger, killing more than 500,000 Americans as of this writing, infecting more than 28 million others. Our efforts to mitigate the spread of COVID-19 have resulted in an economic slowdown unparalleled in many aspects for nearly a hundred years. More people have been unemployed than at any time since World War II. More than 26 million Americans, nearly 16% of the entire US workforce, have been either unemployed, otherwise prevented from working, or working for reduced pay during the pandemic. And both these sets of consequences have been experienced inequitably. People of color, particularly Black Americans, have experienced greater rates of, and death from COVID-19, than white Americans. Meanwhile, unemployment has been both deeper, and slower to recover, among the same minority groups who are already bearing the brunt of the COVID-19 pandemic. It is then little wonder that 2020 also saw protests about racial inequity that were probably the largest civil protests ever in American history.

Politics and the Three Crises of 2020

These three crises unfolded against a backdrop of extraordinary political dysfunction. Since early 2020, messages about, and the handling of the pandemic acquired a political hue. President Trump moved quickly to minimize the threat of the pandemic, repeatedly dismissing the danger posed by the novel coronavirus, and failing to take steps to treat it as a growing and real emergency. Meanwhile, in part in reaction to the president, public health opinion hardened into one of deep concern about the pandemic, prioritizing lockdowns of most economic and social sectors around the country, sometimes with little public deliberation about the potential trade-offs this entailed and how the devastating consequences of this approach would influence health in the long term. Efforts to mitigate the virus became issues seen through red and blue lenses. Mask wearing became a political party signifier, as did one's thinking about whether schools for children should be closed or remain open. Whether or not we should move to protect those living in congregate settings, which included jails, became impossible to consider separate from political leanings. And efforts to mitigate the consequences of the pandemic from falling disproportionately on minority groups became intertwined with political efforts to win over particular groups as the 2020 federal election loomed. In the end President Trump lost the election, exactly the outcome he had tried to ward off in the very early days of 2020 by setting a path of action that rested fundamentally on minimizing the pandemic's threat.

It is perhaps readily apparent on this retelling of the course of the pandemic during 2020 that political actions, and the policies that flowed from them, were inextricable from the consequences of the novel coronavirus that caused COVID-19. Indeed, it is virtually impossible to imagine a parallel world that asks what the course of the pandemic might have been were the political landscape different. The story of COVID-19 must be understood in tandem with an understanding of how, and why politics, policies, and law influence health.

The Causes of Health

The United States spends more on health than any other country worldwide (Tikkanen & Abrams, 2020). Despite that spending, the country's health indicators are worse than essentially all other high-income countries. Americans live shorter, sicker lives than their high-income country peers, despite investing more money in health than all these same countries. This is a rather odd state of affairs and one that, arguably, has little parallel among other American endeavors. Simply put, what other sector does the United States spend more on than any other country, but have worse outcomes than all other comparable countries? This observation challenges us to think carefully about how health is produced, thinking that we should have done long before COVID-19 was ever a consideration.

The mismatch between America's health investment and its outcomes rests on a simple misunderstanding. Health is not the same as health care. While it is commonplace to observe, as I have here, that the United States spends more on health than any other country worldwide, that is not entirely correct. The United States spends more on health care than any other country worldwide. We under-spend on the forces that shape health compared to other peer countries (Dzau et. al., 2020). For many decades the United States has operated on the implicit assumption that health care is the most important factor in shaping our health. That is evidenced by the public narrative around health, symbolized by the lab coat, stethoscope, the caduceus, or the microscope. But this understanding of health is simply wrong. While clearly health care matters — and matters more and more as one advances in age when

health care can offer curative correctives to diseases that emerge over the life course — health care is only responsible for a relatively small fraction of our health. What fundamentally produces our health are the conditions of where we live, work, and play. It is our housing, the quality of our neighborhoods, our access to nutritious food, opportunities for exercise, and whether or not we are exposed to violence that influence health much more throughout the life course than does health care. The latter matters to cure us when we are already sick. The former set of conditions matter to make sure we do not become sick to begin with. And politics, policies, and laws are the fundamental forces that shape the world around us. The quality of housing, whether or not there are guns widely available that facilitate violence, the foods that are subsidized and are widely available, or not, are directly shaped by political decisions, and by the policies that flow from these decisions. The laws that are passed by political actors determine what types of houses are built, where monies are invested to create communities that are walkable, the extent to which we permit pollutants in the atmosphere, and whether we have access to livable wages that in turn allow us to balance work and recreation. These are all a direct result of particular political decisions that then should be appropriately seen as the primary driver of the health of populations.

Rudolf Virchow, the father of microbiology, coined the oft-used aphorism that "politics [is] nothing but medicine on a larger scale" (Mackenbach, 2009). While Virchow made seminal contributions to our understanding of the role of microbes, and how they become disease, he became convinced through his work that social inequality was the cause of poor health, suggesting that unless we aligned those conditions in a way that generated health, we were destined to have worse health than we could have. A particular concern of Virchow's was the observation that the conditions that generate health are unequally distributed, and as such, health inequities emerge that are not addressable without attention to the underlying unequal distribution of health-producing resources. This observation has been repeated in many forms over the past century, and forces such as power, money, and prestige have been called fundamental causes—causes that are inextricably linked to health and inequities in health (Link & Phelan, 1995). This ties the understanding of politics as the foundational driver of health to the emergence of health inequities. If politics favor one group over another, and if politics and policies are central to the determination of health, it is then entirely to be expected that particular groups will be disadvantaged when it comes to health, and that health gaps will be created. Haves and have-nots become health haves and health have-nots, and the foundational driver that shapes the patterns of both is the political decisions, and the policies that flow from them, that distributes health-promoting resources in our society.

This, of course, bring us back into the COVID-19 moment. While it was political dysfunction that was most eye-catching during 2020 and was immediately and intuitively linked to the tragic course that the country took with the pandemic, more fundamentally, it was decades of political underinvestment in the forces that create health that set the stage for how poorly the country did in handling the pandemic. And, it was the unevenness with which the country had invested in the conditions that shape health, the heterogeneity that characterizes the distribution of health-producing resources across socioeconomic and racial and ethnic groups, that set the stage for the socioeconomic and racial and ethnic differences that characterized the course of the COVID-19 pandemic.

COVID-19 and Health Inequities

This is perhaps simply illustrated by considering the disproportionate rate of COVID-19, and the disproportionate death rate from COVID-19 among Black Americans compared to white Americans. Black Americans have died at a rate roughly two times greater than white Americans throughout the pandemic. The rate of death for Black Americans is still less than those among Native Americans, and only a bit higher than those among Latino Americans — all substantially higher than the rates among white Americans—the country's majority group. While these data have been amply publicized and, appropriately, the subject of much public discussion, we have perhaps not paused enough to ask: why? And more specifically why have Black Americans had higher rates of infection, and separately, why have they had higher rates of death once they have been infected by COVID-19?

The answers to the two questions are different, but both illuminate the central role of politics in determining health and health inequities.

First, risk of transmission of an infectious disease that is transmitted person-to-person is directly determined by the likelihood that someone is in contact with other individuals. Therefore, the risk of acquiring COVID-19, particularly early in the pandemic, was determined by whether one could socially distance, and do so quickly. And the extent to which one could do that is socially and economically patterned (Jay, J, et al., 2020). We know, for example, that individuals in the upper quartile of income are more than six times more likely to be able to work remotely than those in the lower quartile of income, as the latter category includes many with service and retail sector occupations that simply cannot be done from one's home. Black Americans are, in turn, disproportionately more likely than other racial and ethnic groups to be employed in these sectors, thereby disproportionately increasing their likelihood of acquiring COVID-19, an observation borne out by the data throughout the pandemic.

Second, risk of severe COVID-19, once COVID-19 is acquired, is a function of many factors, but principally, a function of a person's vulnerability to the infection, and that is linked to prior underlying conditions that have been shown, since the beginning of the pandemic, to be a central determinant of risk of death from COVID-19. The presence of underlying co-morbidities, ranging from heart disease to diabetes is itself racially patterned, with Black Americans long having disproportionately higher rates of disease (Raifman & Raifman, 2020). It is that higher rate of disease then that put Black Americans at higher risk of having severe COVID-19, further embedding the social patterning of the disease.

Understanding these determinants points the way to recognizing the foundational role that politics, polices, and laws play in shaping

health, and during the time of COVID-19, in shaping the patterning of the pandemic. Black Americans have been disenfranchised for centuries, starting with slavery, which shaped the conditions of living for most early Black Americans. This was followed by political actions, from Jim Crow laws, to redlining efforts at segregation, to discrimination in employment opportunities, to harsh penalties for drug-related legal offenses. This is directly linked to lower income, and even lower wealth, held by Black compared to White Americans, and the disproportionate representation of Black Americans in low-income occupations which do not readily lend themselves to remote work. Similarly, these conditions of marginalization led, before COVID-19, to higher morbidity and mortality among Black Americans, which then resulted in a higher burden of underlying vulnerability to COVID-19, manifesting in disproportionate disease severity and death.

It is therefore, literally, centuries of political decisions, and the policies and laws that flowed from them, that determined health of Black Americans before and during COVID-19. This observation has important implications for how we understand health. The higher burden of COVID-19 borne by Black Americans is not due, in any way, to biological difference between Black and white Americans. There is no genetic mapping of particular racialized identities that reflect vulnerability to COVID-19. Rather, it is social and economic circumstances, both long before and during COVID-19 that resulted in the racial patterning of COVID-19, much as these same conditions have patterned health for centuries.

While I use racial differences here to illustrate the more general point, the same argument applies for socioeconomic differences, explaining, for example, the 15-year difference in life expectancy between the poorest and richest Americans and the growing health gaps between the poorest 80% and the richest 20% of Americans (Abdalla & Galea, 2020). The essential explanation for all these differences is the same: social and economic patterning of health producing resources that is determined by politics, policies, and laws.

A Healthier Politics

This brings us back to where we started—the broader determination of health. Dramatic racial differences in the impact of COVID-19 emerged that are not linked to any genetic difference in racial identity, or even in particularly different treatment of racial groups within the health care system. These racial differences are driven by differences in the foundational forces that shape health. While there are some health differences that are influenced by genetic makeup certainly, and while health care is important for health when we are sick, particularly at the extremes of life, these forces are relatively minor players in the architecture of health. If we are to create a healthier country, we need to create a politics that values health, and that recognizes that it is political actors—not doctors—who are the key players in creating that healthier world.

COVID-19 laid bare what has long been clear to careful students of the health of populations. Perhaps for the first time ever, mainstream public media has been discussing social and economic patterning of health, and social movements have emerged influenced, in part, by these same differences. The central question seems whether we shall learn from the COVID-19 moment, and whether we shall recalibrate our politics and policies to the end of creating a healthier world.

The core take-away from the COVID-19 moment is that politics are an inevitable determinant of health. The United States has long operated on an implicit assumption that if we spend enough money on biomedical research, and on curative approaches, we will buy our way out of our poor health. The data have long shown that to be a misunderstanding of how health is generated, and COVID-19 has made that plainly obvious for all to see. Therefore, and critically, the engagement of politics, policies, and laws with health is non-discretionary, and requires an explicit commitment to reorient to health producing politics if we wish to become healthier as a country.

The COVID-19 moment suggests that we care immensely about our health. It is hard to think of another reason but a health threat why we would have upended our entire society within the span of a few short weeks and persisted for more than a year with efforts that constrained our function enormously. This holds promise. It may be that this moment is a teachable one where we can all learn, and one where we can perhaps, embed a more productive way of thinking about health in our national politics, policies, and laws once and for all. To do so will require a wholesale shift in our thinking, informed by scholarship and careful explication of the pathways through which policies and laws can be wielded to promote health.

This Report, which identifies and analyzes the policy challenges and opportunities in light of the pandemic, is a welcome step in that direction.

About the Author

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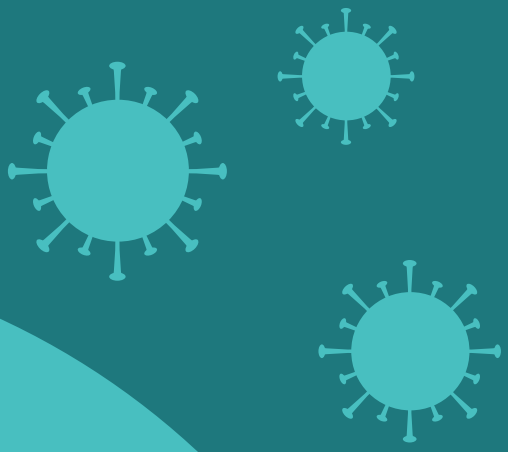

PART 1

Using Government Powers to Control the Pandemic

Policy Tracking in a Pandemic: Lessons Learned

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SUMMARY. The COVID-19 pandemic gave rise to an extraordinarily high volume of legal activity in the United States. In addition to federal travel bans and economic stimulus legislation, states and localities enacted a variety of mitigation measures to combat the spread of COVID-19, including stay-at-home orders, business and school closures, and face mask requirements. Monitoring the state of the law in real time provides information about how government is responding to the pandemic and what rules currently apply. While the prompt documentation of policy change through conventional legal research is critical to the situational awareness of policy makers and the public, not all policy tracking creates the rigorous and reliable legal data required for research. Empirical legal data enables evaluations of the direct effects and side effects of legal measures on health and health equity. Now more than ever, law must be a primary target for health research. This Chapter describes the methods used to create credible data for evaluation research, discusses policy tracking efforts during the COVID-19 pandemic, and closes with reflections and recommendations for supporting scientific legal tracking in the future.

Introduction

The U.S. legal response to COVID-19 has been unprecedented in the volume, speed, and variety of measures deployed. While the federal government issued international travel controls and some policy guidance, most legal action took place at state and local levels. In March 2020 and April 2020, state and local governments began to issue and update emergency orders at a furious pace. By July 1, 2020, state governments issued more than 1,000 legal measures, including mandatory stay-at-home orders, gathering bans, business and school closures, and face mask requirements. See Chapter 1 in *Assessing Legal Responses to COVID-19: Volume I* for a detailed chronology of the federal, state, and local response. As reported in that Chapter, restrictions were relaxed, and the partial reopening of businesses began even as a second wave of COVID-19 cases surged nationally to a peak on July 24, 2020. The third and deadliest wave began in late October 2020 and persisted through the winter, prompting states and localities to postpone reopening plans and impose new restrictions. In January 2021, the Biden administration issued numerous executive actions to strengthen the federal COVID-19 response, including a mask mandate for federal property and all forms of public transportation, an executive order directing government agencies to facilitate the gathering, sharing, and publication of COVID-19 related data, as well as the establishment of the federal COVID-19 health equity task force. By February 15, 2021, the Centers for Disease Control and Prevention reported 485,164 deaths attributable to COVID-19 (CDC COVID Data Tracker, 2021).

As law emerged as the primary non-pharmaceutical "treatment" for COVID-19 prevention and control, questions about its necessity, effectiveness, and costs have been at the center of response efforts and pandemic politics. Researchers have been investigating these questions from the earliest days of the pandemic, drawing on many kinds of behavioral and health outcome data, from data tracking individual- and community-level mobility, to mortality records. However, the starting point for any evaluation of legal interventions is data accurately capturing the key features of the law being assessed. Key features that are essential for legal measurement include the people and places the law regulates, the specific behavior required, allowed, or forbidden, and the exact date the law went into effect. While many organizations jumped to compile and publish daily news of legal developments, which satisfied the needs of policy makers, the press, and the public, most of these resources did not provide the precise legal data required for evaluation research. This Chapter discusses law as a primary target for health research, describes the methods required to create data reliable enough for rigorous evaluation research, highlights various resources tracking COVID-19 mitigation measures, and concludes with reflections on the need for further investment in scientific legal mapping.

Law as a Primary Intervention in Health Research

With law central to the pandemic response, there was immediate interest in research that could assess initial efforts, like the Wuhan, China, lockdown and early border restrictions. There was even more interest in predictive modeling that used early infection

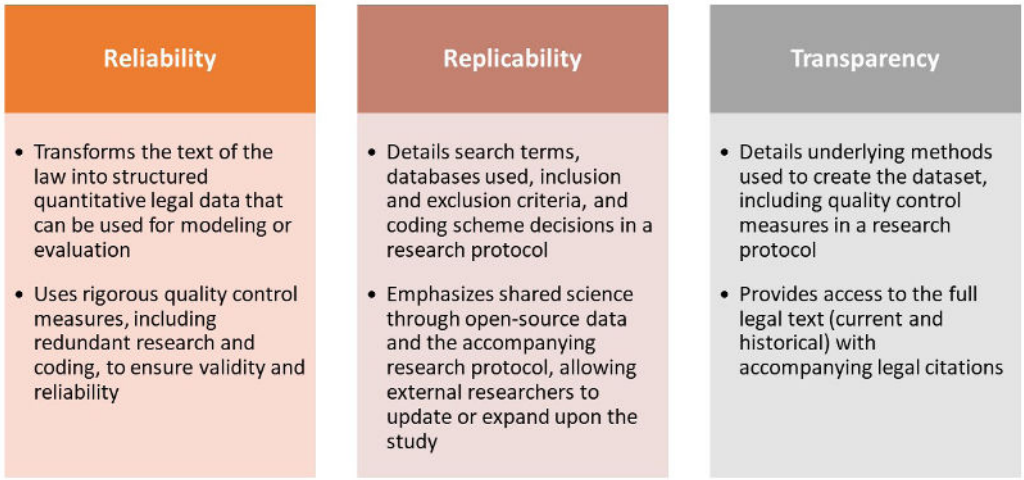
and movement data (and educated assumptions) to predict the course of the pandemic given various legal measures. As time passed, there was increased opportunity to use actual, rather than predicted, values to evaluate the impact of legal interventions on health outcomes. As more jurisdictions passed different legal interventions at different times, the potential for using strong quasi-experimental methods grew. Quasi-experimental designs require robust legal data that is granular (capturing key features of the law that are essential for legal measurement) and longitudinal (capturing the law in each jurisdiction as it changes over time).

The need for robust legal data was evident in preliminary legal evaluation studies that assessed the impact of the timing and/or presence of legal interventions on the virus' spread by evaluating legal responses at the national and state level (Flaxman et al., 2020; Lurie et al., 2020). These preliminary studies relied on legal information from a variety of sources including news stories, press conferences, and government websites. Relying on legal information from these sources, as opposed to legal data created for research, can introduce inaccuracies and inconsistencies in the data, especially when it comes to collecting the effective date of a particular legal measure for longitudinal analysis. Inaccurately or inconsistently capturing the date of an intervention — even if the difference is a few days — can have a meaningful impact on the results, especially given the inordinate frequency of legal measures issued during the pandemic. Further, news stories and press releases often summarize the law, obscuring meaningful nuance within the legal text that is necessary for measurement. Granular features of the law, such as the type of school regulated (e.g., some countries kept elementary schools and preschools open while closing high schools and universities), or the precise size of a gathering ban (e.g., 50 people or 500 people) were not included or were miscategorized in these preliminary studies (Flaxman et al., 2020; Soltesz et al., 2020). Solely relying on information created for general public consumption, as opposed to legal data created for research, can lead to mismeasurement of the law, creating internal validity issues and skewing study results.

The methods used to create legal data for research have gained traction and attention in recent years, as the scientific legal mapping technique of policy surveillance has become a well-defined practice within the growing field of legal epidemiology (Burris, 2017; Horwitz et al., 2020; Kavanagh et al., 2020; Tremper et al, 2020). Policy surveillance — the systematic, scientific collection and analysis of laws of public health significance — tracks key features of laws across jurisdictions and over time, converting the text of the law into numerical data through an iterative process that emphasizes the importance of quality control (Burris et al., 2016). Use of rigorous quality control measures helps ensure accuracy of legal data. Further, good research builds quality and credibility through transparency. Therefore, legal data resources should be accompanied by a clear description of the scope, research methodology, coding rules used to create the data, and a detailed record of quality control measures. Ultimately, the policy surveillance process ensures reliability, replicability, and transparency in creating legal data for health outcomes research (see Figure 1.1).

Although the development of legal data through scientific legal mapping methods has become increasingly efficient due to well-honed methods and the reliance on innovative technology, tracking COVID-19 mitigation measures presents unprecedented challenges. These challenges include the volume of orders and the speed at which they have been issued and amended. In addition, many government websites did not publish historical orders (as they were habitually overwritten or removed) and current orders were often only accessible in PDF format, making the law difficult and time-consuming to collect. Further, with the variety of regulations during an evolving pandemic, the key legal variables changed rapidly, making it particularly difficult to track them consistently. Despite these challenges, many organizations began to track legal activity related to the pandemic in March 2020.

Figure 1.1: Core Tenets of the Policy Surveillance Process.



Policy Tracking in a Pandemic

The rapid speed and ubiquitous nature of COVID-19 measures commanded significant interest in policy tracking from organizations around the world, resulting in many modes of tracking by diverse stakeholders. Universities, academic research institutions, news outlets, and advocacy organizations have compiled and published resources tracking emergency declarations, mitigation policies, and other topic-specific legal interventions in response to COVID-19 at various jurisdictional levels since March 2020.

The content, structure, and utility of COVID-19 policy tracking resources varies tremendously (see the sample of resources in Table 1.1). Policy tracking resources can focus comprehensively on multiple legal measures related to COVID-19, or on policies within a specific area of law and/or a specific population, including areas of law that disproportionately affect Black, Indigenous, and people of color (e.g., mandatory school closures, the regulation of correctional facilities, and paid sick leave laws). Though all of the resources in Table 1.1 provide useful information for policy makers, the press, and the public, not every tracker provided structured legal data, and the accompanying information necessary for researchers conducting evaluations (Center for Public Health Law Research, 2020).

Table 1.1 highlights some of the most important features for facilitating the use of legal data to evaluate law as a primary intervention when conducting health outcomes research.

Jurisdictions. Law and policy can vary tremendously from jurisdiction to jurisdiction, creating natural experiments across continents, across the United States, and across localities within a state. Identifying the jurisdictions selected for measurement is necessary since the location that is being regulated is an identifying feature of the law itself. All of the policy resources in Table 1.1 clearly noted the jurisdictions selected for measurement.

Table 1.1: Sample of resources tracking COVID-19 law and policy measures.

Resource	Jurisdictions	Effective Dates	Structured Data for Download	Links to Legal Text	Transparent Methods
Boston University COVID-19 U.S. State Policy Database	U.S. states	X	X	X	X
BroadStreet COVID-19 Data Project	U.S. states and select cities and counties	X	X	X	X
Kaiser Family Foundation State COVID-19 Data and Policy Actions	U.S. states	X		X	
LawAtlas COVID-19 State Emergency Declarations & Mitigation Policies	U.S. states	X	X	X	X
National Association of Counties County Explorer	Over 800 U.S. counties	X		X	
New York Times Coronavirus Restrictions	U.S. states			X	
National League of Cities COVID-19: Local Action Tracker	Over 520 U.S. cities	X		X	
University of Oxford COVID-19 Government Response Tracker	Over 180 countries and U.S. states	X	X	X	X

Effective Dates. To understand the influence of a particular law on health, a researcher must collect the correct effective date — the date the policy officially went into effect and became enforceable. This allows for an accurate comparison between policies and health outcomes that may change over time. Some resources published a date associated with the measures they tracked; however, it was not always clear whether that date represented the date the measure became effective, the date the policy was announced in a press conference, or the date the order was issued. A research dataset should also contain the date the law ceased to be effective by virtue of repeal, amendment, or a sunset provision (or for current law, the date of the most recent observation verifying the data).

Structured Data for Download. Research use of data is greatly facilitated when laws are translated from unstructured, written text into structured numerical data. Structured, downloadable data equips researchers with quantitative legal data that can be easily merged with health outcome data using classical statistical software packages. Structured data can be cross-sectional (capturing the law at one point in time), or longitudinal (capturing the state of the law over a period of time).

Access to longitudinal data is important because it allows researchers to evaluate the effects of changes to laws and policies. Many resources did not comprehensively capture COVID-19 actions longitudinally and instead only provided the link to current COVID-19 measures, often overwriting older actions that were previously available. Several resources also shared their legal data through Github, which allows for the open-source sharing of information with version control to organize any prospective updates to the data in the future.

Links to Legal Text. Providing access to the underlying legal text used to create the reported data ensures transparency. Most COVID-19 policy trackers provided citations and direct links to the original written policies themselves. This allows researchers to go directly to the source to verify the findings. In fact, most resources included disclaimers encouraging data users to check the policy sources themselves.

Transparent Methods. Resources publishing data for research should be accompanied by detailed methods explanations describing how the data were compiled and manipulated, including coding decisions and discussion of quality control steps. Most resources provided an overview of the process used to collect the data, but very few actually defined coding decisions for specific variables. This lack of transparency and detail can lead to errors in measurement and incorrect conclusions in evaluation studies, as described above.

COVID-19 policy tracking resources serve different audiences with different needs. Aside from the sample included in Table 1.1, many resources did not include effective dates, structured data for download, comprehensive longitudinal data, or methods details. Without these key features essential for scientific legal measurement, the underlying information provided within these resources is not suitable for evaluation research. As described above, quasi-experimental evaluations of law call for longitudinal legal data, with great attention paid to the accuracy of the effective dates of the interventions, along with specificity and granularity when assessing the legal measures.

Reflections on Supporting Scientific Legal Mapping for Health Research

Scientific legal mapping techniques, like policy surveillance, were developed to create legal data suitable for empirical evaluation. The widespread use of these techniques requires core support in its infrastructure and funding. Infrastructure is not only created and sustained through guiding principles, texts, and methods literature, but also through the training and maintenance of a dedicated workforce. Ensuring that researchers who conduct scientific legal mapping are properly trained and have experience with these methods is crucial to building workforce capacity. With the emphasis on quality over speed, even a team of experts requires adequate time and funding to engage in scientific legal mapping. The health research field at large needs to recognize the value in robust legal data in order to demand resources required to maintain the necessary infrastructure. To garner the support needed to spread the use of scientific legal mapping, researchers, peer reviewers and consumers of scientific research on law must demand the same level of quality in legal data as they do in other kinds of data.

Scientific legal data can be difficult to create and time-consuming to maintain, particularly in real time. Scientific tracking in real time is possible with the necessary resources, but there are limits to how fast it can be done. It remains to be seen whether scientific legal mapping, including traditional policy surveillance methods, can meet the public demand for real-time information. The flexible methodology allows for slight tweaks (e.g., crowdsourcing parts of the research process), however, the core tenets of the policy surveillance process must be maintained, and any trade-offs impacting data quality (e.g., reduction in the level of quality control) should be carefully considered. Crowdsourcing parts of the research or legal coding process can leverage networks, build new relationships, and speed the data creation process. Self-reporting and other crowdsourcing methods could be especially useful in underrepresented communities or tribal territories, where policies may be more difficult to access. Machine-assisted research is another potential solution. These types of force extenders could be particularly helpful in gathering local data given the large number of jurisdictions that could be included.

The importance of evaluating law as a primary intervention in health research cannot be overstated, particularly amid a pandemic that gave rise to the rapid implementation of policy as a leading response effort worldwide. While the prompt collection and diffusion of legal change is critical to information sharing and situational awareness, legal evaluation studies demand rigorous legal data, which can be created using scientific legal tracking methods.

Sufficient infrastructure and funding are needed to support the widespread use of scientific legal mapping, particularly during a pandemic when timely and rigorous research is essential to

learning which mitigation measures help and which harm our health. This type of policy tracking is necessary to create the legal data required not only to effectively respond to the current pandemic using science and data, but also to bolster public health infrastructure in the future.

Recommendations for Action

- **For funders: fund policy surveillance and legal evaluation research**. As part of implementing President Biden's Executive Order on Ensuring a Data-Driven Response to COVID-19 and Future High-Consequence Public Health Threats, federal agencies should fund policy surveillance efforts to create, update, and maintain longitudinal legal data related to the COVID-19 legal response in the United States. Health philanthropies like the Robert Wood Johnson Foundation, which supported the creation of a few of the policy tracking resources in Table 1.1, are critical to providing and maintaining the necessary infrastructure and resources to support ongoing scientific legal mapping. However, for law to be studied and evaluated with the same rigor as is used for other interventions of importance to population health, research centers and agencies like the National Institutes of Health must recognize, and invest in, law as a primary target for health research.
- **For state and local governments: make laws and policies accessible for policy surveillance to facilitate legal evaluation studies, ultimately supporting evidence-based policymaking.** When enacting laws or establishing policies in response to a public health crisis, consider ways to support the creation of longitudinal legal data by ensuring all legal text (including historical versions) is accessible to the public. The creation of legal data will provide researchers the foundation for legal evaluation studies, which can ultimately support evidence-based policy making at the state and local level.
- **For researchers conducting policy tracking: Incorporate the core tenets of the policy surveillance process — reliability, reproducibility, and transparency — into your legal measurement methods.**
- **For researchers evaluating the effect of COVID-19 legal interventions on health and health equity: integrate variables that focus on equity and use rigorous legal data as the foundation for your analyses.** COVID-19 has disproportionately affected Black, Indigenous, and people of color in the United States in terms of their health and economic wellbeing. It is essential that studies of policy responses to any public health crisis include measurements of equity. This could be done by choosing legal variables that could have a greater bearing on marginalized communities (e.g., business closures and eviction moratoriums), and by selecting jurisdictions that may be disproportionately impacted by the laws being tracked (e.g., Tribal jurisdictions and localities with a large Black population).

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Is Law Working? Where COVID-19 Legal Epidemiology Goes from Here

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SUMMARY. There was plenty of well-tested public health knowledge about virus control long before COVID-19. We had a good sense of the strengths and limitations of surveillance, information sharing, rapid case finding and contact tracing, quarantine and isolation. For many reasons — including the characteristics of the SARS-CoV-2 virus, the attempts by Chinese local officials to suppress information, and the deliberate reduction of U.S. public health capacity — this approach was rapidly overwhelmed, thrusting the United States (and most of the world) into the far less familiar territory of trying to stop large-scale community spread. Leaders used emergency authority to throw up barriers to viral transmission, from stay-at-home orders to mask wearing, often in apparently haphazard combinations. It would have been possible to draw on expert knowledge and evidence of the use and effects of similar measures in long-ago epidemics of polio and influenza, but we see little evidence that decision makers did so, let alone that they benefited from existing scientific knowledge about law and human behavior in selecting and deploying new interventions. Although hundreds of researchers jumped to assess initial measures, the effort to quickly model, rather than painstakingly measure, the effects of policy, shortcutting peer review, and feeding research directly to the press and social media may have done more than harm than good. The predictions were not good enough, and have not helped us untangle the effects of policies alone or in combination. Looking forward, we hope that new leadership will bring a broader range of existing theory and expertise to bear in fashioning national guidance for COVID-19 control. We recommend significant investment as soon as possible in research assessing the deployment and effects of the emergency measures we are deploying, which in the long term can instigate and guide reform of emergency public health laws and their implementation in future pandemics.

Introduction

Our assessment of how law was working as a tool for reducing the spread of COVID-19 in Volume 1 began with theory. Understanding how law usually works to change behavior and environments is essential to selecting plausible control strategies and interpreting the results of the earliest research. For more information, please see Chapter 2 in *Assessing Legal Responses to COVID-19: Volume I* (Anderson & Burris, 2020). The early research we reviewed in early summer 2020 consisted of simple correlations of legal strategies and trends in COVID-19 disease, and more ambitious and complicated modeling studies. Both kinds of analysis were coming out quickly, often spreading as "working papers" before the completion of peer review or formal publication. Looking at the evidence as it was, we reached four conclusions:

- "Traditional" epidemic control measures of case-finding and individual control could work for COVID-19 provided they were properly and timely implemented.
- Population-based physical distancing measures such as business closures, stay-at-home orders and gathering bans could suppress transmission while they were in effect, but we knew very little about what combinations or stringency or enforcement elements were necessary or sufficient for impact.
- Universal mask-wearing looked effective in reducing transmission rates, but mandating it in the United States posed a serious implementation challenge, first because of initial contrary advice, and then because of its transformation into a symbol of political affiliation.
- Legal measures to control COVID-19 have not prevented and may have contributed to significant racial disparities in U.S. infections.

In this update, we consider the future of COVID-19 control (and public health law research on pandemic control) from the standpoint of legal epidemiology. We have long argued that rigorous public health law research should figure more prominently as a guide to — and check on — policy. We have also recognized that laws are often made in response to new threats, when policy just cannot wait for specific evidence. In cases like that — in cases

like COVID-19 — we have pointed to the usefulness of existing research knowledge and theory in developing new policies, and the importance of "catching up" with evaluation research as quickly as possible. COVID-19 has shown how important — and hard — it can be to follow this advice.

Where We Stand Today: The Old Evidence and Expertise Is Still the Best Evidence and Expertise

It requires no empirical validation to assert that competent and engaged leadership from the president and the federal government is indispensable. Its absence — and the malign efforts of the president to undermine control efforts — would probably have been enough on its own to prevent a successful response (Wright, 2021). We assume that henceforth we can count on minimal competence and a sincere desire to help at the federal level. The research from the past year supports only tentative causal inference, so the following observations about "what works" in legal controls of the virus are offered with an explicit caveat emptor.

Social and Political Limitations Are Intrinsic Elements of Intervention Effectiveness

When we ask what measures "work," or whether governments are doing a "good job," it is important to emphasize that there is no meaningful assessment of COVID-19 control measures outside their specific social context. Resistance to measures like social distancing, mask requirements, and travel controls has been seen throughout the world. The usefulness of any control measure depends not on its potential effectiveness under optimal conditions but rather on its functioning and effects in the typical conditions of real life. Social factors are also crucial to understanding failures of intervention timing: repeatedly, we have seen important controls come too late in an epidemic wave, be removed too soon, or both. It seems to be a common feature of pandemic response that the social and political conditions necessary to adopt or sustain a painful control measure will not be present at the time the measure would be most effectively deployed. This "Pandemic Control Paradox" suggests that the overarching legal evaluation question ahead of us is not whether particular measures can work if timely adopted with adequate resources, but whether and under what circumstances societies are capable of investing in capacity and accepting in time that action is required.

The United States Currently Lacks the Capacity to Control an Outbreak of Readily Communicable Disease through Traditional Case Finding and Control Methods Alone

In early 2021, the United States is further than ever from a level of infection that can be managed by traditional control measures alone. Events show that efficacy of those measures is a function of capacity and implementation. Underfunded and ill-prepared health systems, using poor data systems, unsupported by clear, consistent, and vigorous federal guidance and messaging, are quickly overwhelmed. State and local governments urgently need CDC expertise and funding to increase their capacity to identify and disrupt outbreaks, while implementing vaccination campaigns. Without that, we can best regard traditional control measures as a relatively weak component of the "layered" approach, to which we turn next.

The "Swiss Cheese" Approach Can Work, but Lack of Expertise and Evidence Has Hampered Its Effective Use and Reduced Policymaker and Public Confidence in the Face of High Costs

Like most of the rest of the world, the United States has settled into a layered (or "Swiss cheese") approach to control. In this model, multiple interventions like mask requirements and physical distancing are combined to minimize viral transmission. This approach is supported by some evidence and long-ago experience from polio and influenza control (Bootsma & Ferguson, 2007; Markel et al., 2007). As we concluded even six months ago, these measures can suppress COVID-19 transmission.

The layered approach is forgiving of evidentiary uncertainty and implementation problems. The combination of enough imperfect layers can control outbreaks if the layers are adopted early, broadly, and for a period long enough to substantially suppress community transmission. On the other hand, layering by definition means more things for people to object to, and so may heighten the political and social resistance problem. The lack of evidence on how individual layers work and interact can feed disputes about tradeoffs and alternatives, such as whether closing bars and businesses makes it safe to open schools. In the United States, the spring of 2020 turned out to be the high-water mark of the layered approach, with most states imposing multiple layers of strict control for several weeks or months. Overall, these measures were associated with success in "flattening the curve." Consistent with the Pandemic Control Paradox, some states removed restrictions when rates were still climbing, and many, if not most states were too slow to reapply control layers as infection rates began to climb again.

This failure has many authors, but we want here to focus here on how the problems with multi-faceted pandemic response can usefully be addressed in the future as problems of evidence. Three broad kinds of research and expertise can help policymakers escape the jaws of the Paradox.

First, the selection and design of the layers can be better informed by evidence and expertise on the human factors in pandemic control (Sgaier & Saldanha, 2020). Past research, including a shelf of excellent outbreak histories on U.S. pandemics like cholera, smallpox and influenza, plus a credible literature and repeated experience in public health communication, shows that human beings will react to pandemics and control measures in human ways that reflect their socio-economic, cultural, and political standpoints. Anti-vaccine sentiments and Black mistrust based on medical racism are well-recognized examples in the news now, but nearly all behavioral recommendations in public health run into social and psychological complications that decades of research has worked to explain and address. Similarly, why people obey the law is one of the better-studied domains in sociolegal research. We know a great deal about health communication, and even the social-psychological mechanisms of political polarization, yet evidence and expertise in these areas seem to have rarely been enlisted in control planning or implementation.

Second, it will help next time to have specific evidence on the relative costs and benefits of individual layers and combinations of layers. This knowledge can help policymakers pick restrictions

to impose and give them the confidence to stick with them in spite of resistance. For example, all places where people congregate do not present the same risk, and, more importantly, places are just one component of a more complex transmission system comprised of networks of people with varying socioeconomic status moving through the world. An independently owned grocery store in the Bronx may simply, by virtue of its size, who comes there, how often, and how long they shop have a very different role in community transmission than a Whole Foods in suburban Westchester County (Chang et al., 2021). It is possible, maybe at this point we can say likely, that allowing schools to continue to operate in-person is a net positive when both costs and pandemic control are considered, but only if other settings, like restaurants and bars, are shut down (European Centre for Disease Prevention and Control, 2020; Fisher et al., 2020).

Finally, inattention to structural inequality, and lack of legal epidemiology research and expertise on how law sorts people to poorer health outcomes based on their social position, was part of the reason that equity has been more a matter of talk than action in the COVID-19 response. The failure to center equity has been a tragedy in moral and practical terms. It was obvious from the start that some people would be more vulnerable because of their jobs, their living conditions, and their economic precarity. The CARES Act was a down-payment on addressing some of these issues, but nothing like a long-term solution. As summer waned into fall, the lack of congressional action to help economically stressed Americans not only made their lives harder, but very probably increased the intensity of resistance to layered controls. Without determined and deliberate action, most response measures will have disparate impact or even aggravate disparities. This leads to our next conclusion.

Socioeconomic Inequality Is at the Root of Our National Vulnerability, But Remains Far from the Center of Our Legal Response

The importance of social context to understanding control measures is seen in the disproportionate toll that COVID-19 and the control measures deployed have taken among poorer people and people of color in the United States (Abrams & Szefler, 2020). This disparity is just a downstream manifestation of upstream problems. Our national vulnerability to the spread of the virus, including our vulnerability to leadership and infrastructure failures, should be acknowledged as symptoms of growing inequality. Institutions and services geared primarily at poor and otherwise marginalized people were already starved of resources or shut down altogether. In contrast, societies with less socioeconomic inequality invest more in their people, suffer fewer social ills, have higher levels of social trust, and have better governance. Disparities will continue to plague the U.S. experience of COVID-19 unless and until the avoidance of disparate impact and the amelioration of structural inequality and racism become explicit drivers of control policy.

Legal Epidemiology Moving Forward

As the national research establishment faced COVID-19, the National Institutes of Health pumped more than $3.6 billion into biomedical research. The Gates Foundation added $350 million. But, at a time when hundreds of thousands of lives, the development of millions of children, and billions of dollars in economic activity all depended on questions about control measures, enforcement methods, the organization of the health system, and the many ways law was immediately influencing vulnerability and resilience, little to no money was directed toward public health systems research and legal epidemiology.

Neglect of law in health research is nothing new. Between 1985 and 2014, NIH funded just 510 extramural research grants on the health effects of laws or enforcement practices — less than 0.25% of all funded grants (Ibrahim et al., 2017). It is past time that the organizations and leaders running health research appreciate that law is more like pharmaceuticals than they imagined — laws are treatments applied to millions of patients for years and years, and their many effects can and should be understood better and sooner. Like all health research, legal epidemiology requires an infrastructure that starts with doctoral and post-doctoral training and assures the stable, long-term support necessary to make a good career doing good science. It requires professional organizations to serve as homes for sharing research and promoting better methods and theories.

Waiting for a pandemic to start is not a good way to do basic legal epidemiology. Rapid response research, particularly modeling, has turned out to be less helpful and potentially more disruptive than we might have wished. For example, a paper in published in *Nature* in June 2020 claimed to show that complete lockdowns — and not social distancing, self-isolation, school closures, or public events bans — were mostly responsible for flattening curves in Europe in the spring (Flaxman et al., 2020). The paper was widely reported and apparently influential, unlike a generally ignored critique published six months later that revealed problems in the measurement and modeling of variables striking at the heart of the findings (Soltesz et al., 2020). That is water under the bridge, but now is the time to invest in the research and research infrastructure to learn what we need to know for the future. To unwind the Paradox of Pandemic Control, and fully understand how legal factors influenced COVID-19 and the control response, we need a significant investment of research talent and funding. In this section, we identify a set of important legal epidemiology research questions that should be answered.

Questions about the Legal Infrastructure

The United States has a complex multi-level federal public health system built out of law. The set of legal jurisdictions, powers, and limitations has never been extensively or systematically studied as a factor in system performance. In the wake of a glaring breakdown of that system, it is the right time to figure out how that breakdown happened and what changes beyond leadership and luck will help it perform better in the future across all health threats and functions. The research agenda includes how the current powers, duties, and organizational status of federal health agencies influenced the coordination and support of local, state, and federal health agencies. Similar research is needed on the legal organization of local and state public health systems. We have evidence at the

local level, for example, that health departments with independent policymaking boards of health are more effective than those without. What other structural features determine agency effectiveness at the local and state level? For all these agencies, analysis of legal structural characteristics will have to incorporate the mediating influence of funding.

Public health systems are large and slow to change, but the pandemic provides both a stress test and an opportunity for action beyond COVID-19 and emergency response. The big and obvious failures related to COVID-19 tests, shortages of personal protective equipment, and contact tracing have much to say about the daily operation of public health infrastructure in controlling obesity, road injury, and other harms. Central to this agenda, as discussed in other chapters, is the study of the flow of information and the impact of legal "frictions," like privacy law, that may limit beneficial and low-risk data uses and sharing.

Finally, research on what public health "means," including research in the "law and society" tradition, is sorely needed to get at drivers of health system finance and operation. This kind of research will also inform broader understanding of public attitudes toward control interventions, and why elected officials and public health officials were so often unwilling or unable to effectively build broad support for the specific measures to which we turn next.

Questions about Legal Interventions

Knowing what works in a social context will be crucial to controlling future threats. As illustrated well by COVID-19, efforts to address particular health threats rarely involve only one law, and laws are only one mode of intervention. The layered response to COVID-19 has included many different kinds and variations of emergency rules, and regulations have been accompanied by public education and economic support interventions. With time, money, and talent, research can go some way in untangling the effects of the individual response elements or combinations of elements. With granular data on the frequent changes in policy details, across many jurisdictions, and with better data on outcomes like infection and mortality, these natural experiments in COVID-19 control can yield considerable insight into pandemic control.

Using law effectively will require basic research on how law works (the mechanisms of legal effect) including research that tests generic mechanisms like deterrence (possibly in randomized controlled trials). This kind of research will look at the human factors that determine whether people see control measures as collective protective action or arbitrary violation of civil rights. It will explore how and to what extent supportive policies like the Paycheck Protection Program influenced attitudes and compliance. It will look also at implementation, and how it differed in different places and with differing levels of resources and leadership support.

Questions about Law as a Fundamental Determinant of Health

As Sandro Galea explains in his introduction, good health over the course of life depends largely on access to the resources that support good health and protect against stressors that produce poor health. These "fundamental social causes" of disease influence multiple disease outcomes, through multiple risk factors, by shaping access to key resources and reproducing inequality through intervening mechanisms (Phelan et al., 2010).

Law is both a force that shapes social institutions and hierarchy, and one of the mechanisms that sorts people to different health experiences and outcomes based on their social status. The list of important questions posed by COVID-19 could well start with assessment of whether and to what extent places with different policy characteristics (from the size of the minimum wage (Van Dyke et al., 2018) to the ideological character of its governance (Montez et al., 2020)) had measurable differences in the course or severity of the pandemic. The unprecedented individual payments in the CARES Act and its successor amount to a natural experiment testing the potential impact of a universal basic income policy.

The research agenda moving forward must include research on how seemingly neutral systems treat people differently based on race or socioeconomic position. Studies could look at lack of mandated vacation, childcare, and paid sick leave; low wages; and the behavior of for-profit nursing homes and non-profit (yet bottom-line oriented) hospital systems. Existing regulatory schemes at the state and federal level in areas like occupational health and safety and nursing homes should also be examined as sources of poorer or disparate outcomes. The question of how social inequality and racism influence the policymaking and implementation process is also acute; somehow the fates of meatpacking workers and prisoners trapped in COVID-19 incubators has not stimulated protective legal action, and good research can make it harder to avoid the obvious conclusions and remedies. And lest any reader conclude that research on social determinants of health is just about the health of the poor and marginalized, COVID-19 may well end up illustrating yet again that even the best-off citizens suffer poorer health outcomes where social inequality is high (Emanuel et al., 2020).

Conclusions

Events, and early evidence, continue to suggest that a combination of control measures can suppress COVID-19 transmission. Unfortunately, pandemic response failed to draw on existing evidence and expertise on social determinants of health and the human and social responses to disease and disease control. The world has been rightly impressed by the success of biomedical research in developing effective COVID-19 vaccines in months rather than years. This achievement validates the public's investment in supporting research over decades, because the development of a COVID-19 vaccine was not the work of a year. Developers of the vaccine were building on decades of basic science, particularly in genetics. It bears mentioning, too, that researchers in both academia and commercial pharma were equipped with first-rate labs and computers, and plenty of well-trained and well-paid colleagues with well-built career paths to draw on for information and support. Comparable investment and infrastructure have been sorely lacking in legal epidemiology.

The failure to appreciate that law and other social factors can be understood scientifically, and more importantly that the insights provided by science can be used to design and implement policy,

has contributed to the overall dismal record of COVID-19 control. Policy will always be political, and systems comprised of human beings will exhibit frustratingly irrational, selfish, and self-harming behavior. Better research and theory will not change that, but they remain essential tools in the fight for rational, humane, equitable, and effective health policies.

Recommendations for Action

Federal government

- Congress, via the National Institutes of Health, the National Science Foundation or otherwise should launch a major, long-term initiative to support scientific research on the health effects of law and legal practices, starting with the impact on COVID-19.

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Contact Tracing, Intrastate and Interstate Quarantine, and Isolation

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SUMMARY. While contact tracing, quarantine, and isolation are foundational infection control methods supported by state law, systemic and sociocultural challenges arising during the COVID-19 pandemic have revealed limitations to their usefulness in state and local response efforts. These challenges include: the swift, pre-symptomatic and asymptomatic spread of the various virus strains; the lack of ubiquitous access to rapid virus testing; the lack of equitable access to resources and supports to aid low-income, minority, and unhoused community members with successful, voluntary isolation and quarantine; implementation challenges posed by the resource-intensive and highly-localized nature of contact tracing; and the complications faced by state and local health programs in their attempts to foster a level of trust needed to promote voluntary participation in the contact tracing process. Federal courts continued to rebuff legal challenges to interstate quarantine policies. Equity is promoted as a core feature of public health services and the new administration's COVID-19 response efforts, offering promise for expanded and sustained support aimed at addressing disparities in COVID-19 outcomes and services.

Introduction

Contact tracing, quarantine, and isolation are core communicable disease control measures used by public health departments as part of a comprehensive strategy of case ascertainment and reduction of community infection spread. State public health and emergency response laws authorize contact tracing as part of infection control efforts. However, during this pandemic, some states have proposed or passed policies reinforcing the voluntary nature of participation in contact tracing and limiting the collection and use of health information derived from the contact tracing process. Legal challenges to interstate quarantine rules have been unsuccessful. Public participation in contact tracing, quarantine, and isolation efforts as part of U.S. response efforts at the national, state, and local levels has largely been voluntary (save a handful of jurisdictions' vigorous enforcement of traveler's quarantines). A lack of ubiquitous access to rapid, accurate testing, coupled with the high share of cases attributable to pre-symptomatic and asymptomatic spread of COVID-19, have combined to overwhelm contact tracing efforts and the monitoring of quarantine and isolation cases. These efforts also have been degraded by insufficient and fragmented funding streams; low levels of public accountability; and concerns about the impact of such efforts on individual privacy, liberty, and travel rights, as well as the financial and personal costs that may arise out of a positive diagnosis. For more information on contact tracing, quarantine, and isolation, please see Chapter 3 in *Assessing Legal Responses to COVID-19: Volume I*.

As exponential spread of the virus during the winter of 2020 has overwhelmed state and local tracing and quarantine monitoring capacity, some health departments have turned to encouraging those testing positive to undertake do-it-yourself close contact tracing and notification efforts, or redeployed contact tracers to other pressing pandemic response duties. The influx of new, more infectious viral strains raise further concerns about whether contact tracing and quarantine will be effective as an infection control measure outside focused use in closed settings with vulnerable populations, such as hospitals, prisons, dormitories, and long-term care facilities. The approval and deployment of multiple effective vaccines promise, over time, a reduction in severe COVID-19-related morbidity and mortality. Adoption of a national pandemic strategy grounded in equity, and the allocation of significant additional federal funds toward state and local pandemic-related efforts, also should, eventually, improve the availability and accessibility of rapid testing and, potentially, for supported and protected isolation of those who test positive. They also offer

promise for greater response coordination, adoption of data-driven best practices, improved public health messaging and community engagement, and a decrease in racially and socioeconomically driven COVID-19-related health disparities.

Factors Impeding U.S. Contact Tracing, Isolation, and Quarantine

The "test-trace-isolate" strategy is frequently employed by public health authorities as a set of non-pharmaceutical interventions (NPIs) to attempt to contain the spread of an infectious disease. In addition to rapid outreach to those receiving positive tests, encouraging them to isolate themselves from others, and monitoring their adherence with the isolation request, public health departments also attempt to break up infection chains by rapidly identifying who the newly-diagnosed individual may have potentially infected prior to their diagnosis, communicating with those "close contacts," encouraging both groups to get tested and to quarantine until their diagnosis is returned, and monitoring those individuals.

Over the course of the pandemic, we have found that the factors contributing to the effectiveness of these interventions are numerous, varied, difficult to distinguish from one another and, after a year of largely fragmented, often inconsistent federal, state, and local efforts, even more difficult to ensure they work well. As stated by Dr. Alondra Nelson, "What looks like a single problem is actually all things, all at once. So what we're actually studying is literally everything in society, at every scale, from supply chains to individual relationships" (Yong, 2020). The first set of factors concern the nature of the virus itself: A virus that can spread via aerosol, can be transmitted when the infected individual is pre-symptomatic or asymptomatic, or can be transmitted during a short time of exposure (or set of exposures), will be much more readily spread and harder to trace and contain than infections that lack these characteristics. Between March 2020 and September 2020, studies have revealed that about 40% of coronavirus infections are transmitted pre-symptomatically or asymptomatically (Chen, 2020), and that multiple short exposures over the course of 24 hours can result in infection (as opposed to requiring one 15-minute close encounter) (CDC, 2020).

A second set of factors concern the availability and accessibility of test services that rapidly return results. The less available, accessible, and/or timely testing is, the lower the chance that pre-symptomatic and asymptomatic individuals will isolate, the greater the opportunity for undetected spread of the virus, and the harder it becomes to determine who might be close contacts of those individuals. The U.S. testing system continues to be plagued by inaccessibility and slow testing response rates (Chen, 2020). Availability and accessibility disparities also are disproportionately borne by communities of color and of lower socioeconomic status (National Strategy, 2021).

A third set of factors affect the ability of infected individuals to isolate and/or quarantine for the duration of their infectious period. Due to income, food insecurity, job insecurity, lack of employee benefits, crowded and/or unstable living conditions, lack of access to affordable child care, and other factors, including laws and policies that offer scant supports and protections in these areas to those being asked to isolate, individuals may be unable to safely isolate for the scientifically recommended duration of time. Fear of being isolated or suffering the economic or social consequences of a positive diagnosis may also lead those who are asymptomatic or pre-symptomatic to not be willing to get tested, increasing the potential for the silent spread of the virus through a community. Studies have shown that Black, Hispanic, and Tribal communities and those of lower socioeconomic status have proportionately lower access to these social supports.

A fourth set of factors pertain to the capacity and capabilities of the contact tracing systems in place. The contact tracing process, when done thoroughly, is resource intensive. When a community faces high positive case rates, contact tracing efforts can rapidly be overwhelmed. This results in delays in outreach to those newly diagnosed (ideally new case investigations begin less than 24 hours after a new diagnosis is reported), reduced data collection during the case investigation process, abbreviated or postponed close contact identification and outreach, and decrease in follow-up with those asked to isolate or quarantine. Numerous swamped health departments around the country reportedly suspended contact tracing efforts, encouraging the newly-diagnosed to conduct do-it-yourself contact outreach (Dahlberg, 2020). The effectiveness of contact tracing outreach also is impacted by the connection of those conducting the case investigations to the communities they are serving. In an effort both to protect the health of public health workers and to improve efficiency, many state and local contact tracing efforts have been undertaken via phone or email, using pools of decentralized remote workers to conduct the case investigations, rather than employing people from within the affected communities (Silverman, 2020).

Finally, the success of contact tracing efforts relies upon trust as it manifests in many different forms. Ideally, new cases and close contacts should be permitted to participate in the contact tracing, isolation, and quarantine processes voluntarily. Communities should be engaged early in the planning process and in public education campaigns concerning the importance of these efforts. "Contact tracing begins with engaging communities about the disease, how to protect individuals and their communities, and how to suppress transmission. … Special consideration should be given to planning contact tracing for at-risk and vulnerable groups, including, but not limited to, minority groups, homeless persons, migrant workers, refugees, and others. Communication about contact tracing should emphasize solidarity, reciprocity, and the common good." (WHO, 2020). Fear of, or the lack of trust in, government or the contact tracing process, or a prioritization of individual liberty over the values of solidarity, reciprocity, or the common good, can result in decreased willingness to participate in all aspects of the contact tracing process. Reports of new cases and contacts refusing to share information with contact tracers continue to be widespread (Lewis, 2020).

Updates on Interstate Quarantines

In the latter half of 2020, many states and cities implemented policies imposing quarantine requirements on interstate travelers, and some cities, including San Francisco, have also imposed

regional intrastate quarantine restrictions on travelers to their area from other parts of their own state. A number of other states recommend, but do not require, travelers to quarantine for up to 14 days upon entry into their state (Brown & Marples, 2021). The availability of more ready access to testing services has led many of these jurisdictions to include exemptions or "test out" policies for those who present health affidavits and/or negative COVID-19 tests. Depending upon the jurisdiction, these may be required to be taken before or after arrival in the destination location.

As noted in Volume I, challenges were filed against both the Maine and Hawaii traveler quarantine policies, and in both cases, the Federal District Courts found the policies to be constitutional. In January 2021, the First Circuit Court of Appeals, hearing the appeal of the Maine case, affirmed Maine's authority to issue an executive order requiring travelers to the state to quarantine for 14 days before being permitted to go out in public (*Bayley's Campground v. Mills*, 2021). In upholding the district court ruling, the First Circuit Court of Appeals agreed with the district court's finding that the *Jacobson* standard of deference should not apply. The court agreed that the travel restriction did burden the constitutional right to interstate travel and that, as a result, the policy should be subject to strict scrutiny. However, the court also felt that the state was able to meet its burden. It found Maine's governor had stated compelling interests in protecting both the state's inhabitants from further spread of the virus and the state's health care system from being overwhelmed by cases generated by infectious out-of-state travelers. The state also was able to demonstrate that, at the time the restrictions were put in place, "there were no other effective less-restrictive alternative" means available to serve the state's compelling interests (including recommending rather than requiring quarantine, as the court felt a recommendation would be less likely to successfully slow the virus' spread). Because testing services are more readily available today, it is likely that an order put in place now could be required to include a provision that allows exemptions from the quarantine requirement for those able to demonstrate they are not a risk to infect others (*Bayley's Campground v. Mills*, 2021).

While both Maine and Hawaii have moderated their policies to accommodate access to testing services, Hawaii has remained extremely strict in enforcing their traveler quarantine restrictions, and Hawaiian public health authorities have arrested hundreds of people in the past year for violating state quarantine rules (O'Connor, 2020).

Equity, Stimulus, and the National Response Plan

In November 2020, the de Beaumont Foundation published their updated version of the 10 Essential Public Health Services framework. At the heart of their framework is equity, which they recommend infuse all public health services, and they define as

> "a fair and just opportunity for all to achieve good health and well-being. This requires removing obstacles to health such as poverty and discrimination and their consequences, including powerlessness and lack of access to good jobs with fair pay, quality education and housing, safe environments, and health care. It also requires attention to health inequities, which are differences in population health status and mortality rates that are systemic, patterned, unjust, and actionable, as opposed to random or caused by those who become ill."
> (de Beaumont, 2020).

Contact tracing, quarantine, and isolation efforts, and the laws supporting such public health measures, fit squarely into their framework of essential public health services. As noted in the Section above, as applied, the delivery of these services has not always been equitable.

Recent actions taken by Congress and the Biden White House represent steps toward a more equitable COVID-19 response. In late December 2020, Congress passed a $900 billion coronavirus relief plan. The plan contained several provisions to bolster contact tracing efforts. This included more funding for testing and contact tracing, such as $2.5 billion to develop, identify, and improve such efforts among racial and ethnic minority populations, rural communities, and other high-risk and underserved populations. The bill also requires that states accepting such funds regularly report to the Department of Health and Human Services on their contact tracing plans and efforts (Consolidated Appropriations Act, 2021).

Within 24 hours of President Biden's inauguration, the White House released the National Strategy for the COVID-19 Response and Pandemic Preparedness (National Strategy, 2021). Like the de Beaumont Foundation framework, this strategy is grounded in the goal of strengthening and advancing a U.S. pandemic response effort "driven by science and equity." Numerous provisions focus on building trust in public health response efforts within minority communities. Others offer plans for improving the accessibility and availability of testing, contact tracing, and providing the social supports necessary to undertake quarantine and isolation. The administration proposes providing paid leave to workers going into quarantine and isolation, and expanding child care support and rental assistance to advance these goals. Recognizing that "there must be sufficient workforce to serve the communities in greatest need," the administration also proposes to expand the public health workforce, creating a new United States Public Health Workforce Program of at least 100,000 new, community-based workers to "conduct culturally-responsive outreach and engagement, testing, contact tracing, and other critical functions" (National Strategy, 2021). Such initiatives, if funded, implemented, and executed in coordination with state and local response efforts, could help improve communication and trust with vulnerable communities, facilitate employment opportunities for local residents as part of the public health workforce, and bolster low-income workers' job stability and ability to adhere to public health guidance concerning testing, isolation, and/or quarantine efforts.

Recommendations for Action

Federal government:

- Fully fund and implement the United States Public Health Workforce Program.
- Expand funding for childcare support and rental assistance in low-income communities to improve adherence with quarantine and isolation recommendations.
- Expand federal funding for state and local public health agencies to ensure resilience in the face of massive state and local budget cuts in the wake of the pandemic.

State and local governments:

- Expand job protection and child care benefits to low-income workers to make it easier to adhere to quarantine and isolation efforts.
- Ensure that vaccination-related community outreach efforts are community-engaged efforts, structured to reflect the communities they plan to serve; also include in these initiatives outreach related to contact tracing, quarantine and isolation.

About the Author

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Distancing, Movement and Gathering Restrictions, and Business and Activity Control Measures

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SUMMARY. Community mitigation measures that limit contacts between people can be an effective strategy to reduce the spread of COVID-19. Government powers can be used to require or encourage these measures through an array of social distancing strategies such as movement and gathering restrictions, closure of in-person operations of non-essential personal, recreational, and commercial activities, and physical separation and facemask-wearing requirements. Such strategies have been integral to the COVID-19 pandemic response in the United States. This Chapter examines the legal, ethical, and political issues raised by the government's use of these social distancing strategies, highlighting how state governments in particular have used these tools and how they have been adapted over time as successive waves of COVID-19 cases have emerged. Often politically controversial, numerous legal challenges have been brought against government orders that restrict movement, impose gathering limits, and close businesses. The government has prevailed in most of these legal challenges, due to the deference typically given by courts to government-imposed restrictions that seek to balance public health and other considerations under circumstances of scientific uncertainty. However, recent Supreme Court rulings portend changes to the legal landscape that may render government public health powers more vulnerable to challenge when religious exercise rights are implicated. Government officials have an obligation to take affirmative steps to minimize the need for social distancing orders and to ensure that when restrictions and closures are in place that supportive policies mitigate disparate burdens on vulnerable and marginalized communities.

Introduction

This Chapter explores some of the fundamental, most impactful, and controversial actions taken by federal, state, and local governments to contain the spread of COVID-19. Government officials have implemented widespread, but quite varied, actions to achieve better community mitigation of COVID-19. These efforts have taken the form of layered interventions that aim to reduce COVID-19 spread using some combination of measures that reduce interpersonal contact, expand physical distance when people do come into contact, reduce the intensity of exposure, and introduce physical barriers like masks, screens, and ventilation (see Chapter 2). Government orders imposed restrictions on mass movement; control of personal interactions and property uses through requirements to wear masks and maintain physical separation; and limitations on personal, recreational, educational, and commercial activities to limit the extent of personal interactions that can facilitate transmission of a contagious disease like COVID-19. While many of these social distancing strategies have long been recognized as effective interventions for mitigating the spread of airborne infectious diseases, these measures have not been widely used in the United States. The implementation of these countermeasures has raised numerous legal and political questions and challenges.

Social distancing strategies to mitigate infectious disease spread run along a continuum of restrictiveness, from extensive limitations on interactions (stay-at-home orders; business closures; activity bans; movement restrictions) to less restrictive measures (density or time limitations on in-person gatherings; physical separation; mask-wearing requirements). As the COVID-19 pandemic has continued, the insights of virologists and epidemiologists have allowed for a better understanding of

the risks of this disease and its methods of infection and spread. Despite these insights, decisions about whether and when to use government powers to achieve social distancing have been wildly inconsistent, with some states vacillating between strict restrictions and minimal COVID-19 mitigation measures, and others refusing to take any significant compulsory measures to forestall the spread of the disease. This variation likely stems at least in part from the fact that there are so many options for intervention measures, but no national plan or clear evidence base for determining which combination of measures to apply (see Chapter 2).

The erratic application of community mitigation strategies also has intensified racial and ethnic health disparities. Increased levels of community-based COVID-19 infections have had greater impact on communities of color and indigenous communities (CDC, 2020), who are more likely to live in multi-generation households, work in jobs that require in-person contact, and have underlying health conditions that can increase the likelihood of serious COVID-19 infection and death. Members of these communities also are affected disproportionately by disruptions in public services, paychecks, child care, and mobility (Yearby & Mohapatra, 2020). Protecting the health of these communities requires a more equitable response than has been implemented so far. Robust and consistent government support that provides food, housing, and health services access as well as income, employment, utility, and housing protections can promote equity in the pandemic response and simultaneously allow people to comply with community mitigation strategies to further reduce the spread of COVID-19.

Volume I of this report addressed many of the fundamental legal powers that justify orders implementing distancing measures, movement and gathering restrictions, and closures of or limitations on businesses and other activities, and noted the historical development and application of these powers, including the widespread use of these strategies by states during the first wave of COVID-19 cases in the United States (Gable, 2020). In the second half of 2020, as COVID-19 cases ebbed and then resurged, many states again turned to these strategies, often using less-restrictive and more targeted approaches. The failure of the federal government throughout 2020 to provide leadership or sufficient support to state and local governments, while often actively opposing community mitigation efforts, further complicated efforts to bring rates of COVID-19 infection under control.

Legal authority for these public health measures has historically been interpreted quite broadly at the state and local government levels, based on expansive understandings of the state police power and presumed deference to government officials pursuing urgent public health goals, particularly those designed to stop the spread of infectious diseases (*Jacobson v. Massachusetts*, 1905). While courts have occasionally invalidated government restrictions on movement, interaction, or activity that are overbroad or applied in a discriminatory manner (*Jew Ho v. Williamson*, 1900), government interventions of this sort have largely been upheld. This Chapter examines how social distancing, gathering limitations, mandated closures, and activity bans have been utilized during the COVID-19 pandemic, and how legal challenges to government orders implementing these restrictions have complicated the legal landscape regarding the scope of public health powers available to respond to infectious disease outbreaks. Recent judicial decisions interpreting public health powers (discussed in detail below) have introduced greater uncertainty about the amount of deference that governments will receive from courts when implementing orders that infringe on fundamental rights, particularly rights related to religious worship activities.

Distancing and Control Measures during COVID-19

Government Actions to Control Movement and Limit In-Person Interactions

The use of social distancing strategies by government officials in the United States to respond to the COVID-19 pandemic during 2020 and early 2021 has varied considerably over time and across jurisdictions. State and local governments reacted to the first spike in COVID-19 cases in March 2020 by using emergency powers to implement widespread and wide-ranging stay-at-home orders and other steps to limit personal interaction to contain the spread of the disease. As the magnitude of the outbreak grew, government officials expanded and extended these restrictions to include travel restrictions, limits on the number of people permitted to congregate in non-essential gatherings, closures of in-person operations of schools and non-essential businesses, and requirements for mask-wearing and maintaining physical distance between people, especially indoors.

This initial round of closures, which lasted roughly from mid-March until May 2020 and imposed the most extensive set of layered interventions, seems to have had the intended epidemiological effect on containing the disease, as case rates that had been rising rapidly began to abate (Castillo et al., 2020; Anderson & Burris, 2020). Some states began removing restrictions on gatherings and business operations as early as April 2020, while cases were still rising. The rapid reversal of restrictions allowed for a resurgence in COVID-19 cases in states such as Arizona, Florida, Georgia, and Texas during summer 2020, prompting some of these states to reluctantly re-impose gathering and activity restrictions.

COVID-19 cases again began to rise nationwide in November 2020 to levels well beyond the spring 2020 outbreak. Yet despite this unprecedented surge in cases, most states reacted slowly and did not reenact the same extensive restrictions used the prior spring. Few states imposed full-scale stay-at-home orders, with most states opting instead to apply more limited, regional restrictions on movement and activity. States hit hard by new cases, such as California, implemented regional stay-at-home orders that could be adjusted to account for changes in COVID-19 case numbers, while other states such as Connecticut, Ohio, North Carolina, and Virginia imposed curfews for non-essential activities. Business closures and gathering restrictions reemerged as well—particularly indoor dining and recreational activities, which were curtailed in many states. However, some states refused to impose any restrictions to stop the spread of COVID-19 infections, such as North Dakota and South Dakota, where infection rates have been some of the highest per capita in the world. Other states, such as Iowa and Florida, have maintained relatively lax statewide COVID-19 restrictions and prohibited local governments from implementing stronger mitigation measures despite ongoing outbreaks.

Several reasons may explain why states were more reluctant to use social distancing orders in their responses to the winter 2020-21 surge. First, better scientific understanding of how COVID-19 is transmitted and the relative risks of different types of activities allowed for states to take more targeted interventions instead of the all-of-nothing approach employed at the outset of the pandemic. This approach is consistent with ethical best practices that state orders should seek less restrictive alternatives that will still achieve mitigation.

Second, political and economic pressures made more extensive restrictions harder to impose and may have dissuaded officials from taking necessary steps to mitigate COVID-19 spread. The extensive restrictions in the first wave caused substantial economic and social disruption, even as they effectively "flattened the curve." While federal and state support helped many individuals, businesses, and institutions get though the initial round of closures and restrictions, Congress never sufficiently funded programs that would provide adequate support for people to stay home and businesses and institutions to persist for longer-term shutdowns. Nor did funding or support materialize for a robust test-trace-and-isolate infrastructure that could allow for targeted COVID-19 interventions to break transmission chains as they are discovered. President Trump and conservative activists amplified voices opposed to further COVID-19 restrictions and inveighed against additional social support measures to help struggling individuals and businesses.

Third, the length of the pandemic and the accrual of loss, exhaustion, and strife made stricter interventions less palatable and less feasible. The initial round of community mitigation strategies were supported by impressive and unprecedented sacrifice and altruism by millions of Americans. As pandemic fatigue set in, accompanied by continued political gaslighting and heightened economic concerns, many decision-makers and members of the public alike became more frustrated and resigned to accept high rates COVID-19 infection and death as the "new normal," and the reimposition of distancing measures as politically and economically infeasible. The disconnect — and in some cases outright denial — of many relatively well-off decision-makers from their constituents who were struggling to stay economically afloat exacerbated the resistance to both renewed community mitigation efforts and being open to provide sufficient economic and social support for those most impacted by COVID-19, particularly those in poor and marginalized communities.

During the second half of 2020, mask-wearing mandates became the most visible and contested community mitigation strategy at the state and local levels. Despite ongoing mixed messages on the importance of masks in stopping the spread of COVID-19, mandatory mask-wearing requirements increasingly have been adopted. At the time of this writing (February 2021) 33 states, the District of Columbia, and Puerto Rico have mask mandates in place for non-household indoor settings and six additional states require masks in some settings. Mask mandates have withstood legal challenges, including claims that mask mandates violate due process and constitute compelled speech. The Biden administration has recently implemented a mask mandate on federal properties and for anyone engaged in interstate travel.

All levels of government were slow in responding to the rising pandemic threat in early 2020, but the federal government response was especially anemic and continued to lack urgency, organization, and competence throughout 2020. The Trump administration consistently failed to provide sufficient guidance or leadership to slow the spread of the pandemic, and actively undermined and criticized states that took the lead in targeting restrictions on activities to slow transmission (Parmet et al., 2021).

The federal government's role in effectuating distancing and control measures for infectious disease outbreaks can include coordination, direct action, and the provision of funding and support. The Trump administration largely eschewed this coordinating role. While guidance from the Centers for Disease Control and Prevention (CDC) was influential in helping states craft their policies on gathering sizes, distancing guidelines, and mask-wearing protocols, the president and other federal officials contradicted and questioned these public health efforts, blunting their influence.

Most legal scholars agree that federal executive branch officials have limited powers to directly issue broad orders to restrict movement, mandate distancing precautions, and require masks outside of federal properties and interstate travel. Yet the Trump administration did not apply COVID-19 mitigation measure even in these more limited settings. The CDC's September 2020 nationwide eviction moratorium represents the most expansive use of federal authority to protect public health to date. Using the language found in Section 361(a) of the Public Health Services Act (PHSA), 42 U.S.C. § 264 as modified by regulations, the CDC director found that the halt on evictions was 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." This unprecedently broad assertion of federal executive authority to pursue public health goals has already withstood initial court challenges and could potentially form the basis of more aggressive federal intervention to impose nationwide movement restrictions or masking and physical distancing requirements (see Chapter 10 on federalism for more details).

Finally, the federal government did not sufficiently provide funding and support to allow communities, institutions, businesses, and individuals to comply with movement and activity restrictions. Congress passed legislation in spring 2020 containing some of these supports (such as economic assistance, eviction and utility shutoff moratoria, expanded unemployment benefits), but additional necessary resources languished for most of the year, limiting the ability of states to successfully reenact precautions when they were needed in November and December 2020. Indeed, had supportive measures for small businesses and restaurants been more consistent, it may have engendered less opposition and better compliance with closure orders. Lack of sufficient economic and social support measures has particularly negative impacts on members of racial and ethnic minority groups and the poor, who have faced disproportionate economic, social, and health effects during the COVID-19 pandemic (Yearby & Mohapatra, 2020).

As the Biden administration takes over the reins of government, there is ample opportunity for the federal government to assert a more proactive role in guiding and supporting community mitigation measures. The Biden administration has already issued executive orders requiring physical distancing and masking requirements on federal properties and interstate and international conveyances. The CDC should provide essential guidance to states, localities, and institutions about how to best target and layer community mitigation strategies to achieve significant reductions in COVID-19 transmission. Most importantly, Congress should pass legislation that supports the ability of people, businesses, institutions, and government to comply with community mitigation strategies. Such legislation should provide additional funding for individuals, small business, schools, and state and local governments and extend legal protections against eviction, mortgage foreclosure, utility shut off, discrimination, and employment loss due to community mitigation measures.

Legal Challenges to Government Restrictions

Numerous legal challenges to the use of government powers have emerged since the beginning of the COVID-19 pandemic. Litigants brought cases grounded in a variety of legal theories to challenge the authority of state and local governments to restrict gatherings, limit business operations, and impose other social distancing requirements. Courts have upheld the vast majority of government orders in the face of these challenges. But as the pandemic stretched on, courts — including the newly reconstituted and more conservative U.S. Supreme Court — have increasingly given less deference to state orders imposing social distancing and community mitigation measures, particularly when the legal challenges invoke religious free exercise. In addition, several state legislatures have successfully challenged in court the authority of executive branch officials to impose social distancing measures.

Courts evaluating challenges to state emergency orders have frequently relied on *Jacobson v. Massachusetts*, the famous 1905 U.S. Supreme Court case often considered the legal cornerstone of public health emergency powers. *Jacobson* recognized that the state's interest in protecting public health can outweigh individual liberty interests in legitimate circumstances such as curtailing an infectious disease outbreak, while also noting that state power in these contexts is subject to judicial review. However, since *Jacobson* predates modern constitutional jurisprudence, modern courts have developed differing interpretations of how it applies to challenges to government-imposed COVID-19 restrictions (Parmet, 2020; Wiley & Vladeck, 2020).

At one end of the spectrum, some courts have interpreted *Jacobson* as establishing an extreme deference to state actions that suspends normal constitutional constraints during a public health emergency. The Fifth Circuit's decision in *In re Abbott* is emblematic of this approach, upholding a state law that suspended abortion services as not essential during the declared emergency and finding that courts should defer to state restrictions imposed due to an epidemic unless they constitute "a plain, palpable invasion of rights." Courts have dismissed virtually all challenges to stay-at-home or closure orders brought by individuals alleging violations of fundamental rights to assemble or travel using similar reasoning—that per *Jacobson*, pandemic exigencies rendered the restrictions constitutional without requiring further demonstration that strict scrutiny standards had been satisfied (Wiley, 2020). Likewise, most legal challenges by businesses claiming that government-imposed closures, customer limits, or operating restrictions violated due process and equal protection rights or constituted takings were resolved in the government's favor, with courts finding in all but a few outlier decisions that these orders easily met rational basis standards (Wiley, 2020).

In evaluating challenges to social distancing orders, the Supreme Court initially adopted what seemed to be a cautiously deferential approach to evaluating state powers during a pandemic. In *South Bay United Pentecostal Church v. Newsom* (*South Bay I*), Chief Justice John Roberts explained in his concurrence that a California order limiting the size of attendance at religious worship services to 25% capacity or 100 attendees did not clearly violate religious free expression rights, recognizing deference to "politically accountable" public health officials.

The Supreme Court subsequently changed course, halting two similar government orders that restricted in-person religious worship services in two decisions issued after Justice Amy Coney Barrett joined the Court in October 2020. In *Roman Catholic Diocese of Brooklyn v. Cuomo*, the Court enjoined a New York order that placed limits on the size of indoor religious and other communal gatherings, finding that restrictions affecting religious worship activities that do not similarly restrict secular gatherings — even those that have less significant risks like shopping — were an unconstitutional violation of religious free expression. Justice Gorsuch's concurring opinion harshly criticized the use of *Jacobson* to justify deference to state public health expertise that impinges on religious practice in *South Bay I*. The Court's ruling in *South Bay United Pentecostal Church v. Newsom* (*South Bay II*) went even further to shield religious practice from public health orders, with six justices agreeing to grant an injunction against California's order banning gatherings involving indoor communal activities. While the state order was generally applicable, placed restrictions on both religious and secular gatherings, and provided scientific support for limiting gatherings due to the high risk of COVID-19 infection in these settings, the Court's plurality nevertheless found the measure to be too restrictive to religious worship.

The Supreme Court's recent decisions have upended conventional wisdom about deference to government actions taken to protect public health during epidemics. The Court's willingness to subject social distancing orders that impact religious worship to rigorous strict scrutiny and to second-guess the government's scientific risk assessments and conclusions creates significant uncertainty about when courts will uphold social distancing orders that impact fundamental individual rights. As Justice Elena Kagan noted in her dissent in *South Bay II*, these rulings inject "uncertainty into an area where uncertainty has human costs." While most courts will continue to give the government wide latitude to enact limitations on gatherings, the judiciary may intervene if religious free expression (and perhaps other fundamental rights) are impacted without sufficient justification. State and local governments

should carefully draft social distancing orders to ensure that they are neutrally-worded and do not single out religious gatherings, and should include clear, scientifically-supported information justifying restrictions and explaining the scientific basis for differences in restrictions across categories of activities (Wiley, 2020; Parmet, 2020).

In several states, legislatures brought legal challenges asserting that executive branch officials exceeded their statutory authority in issuing social distancing and community mitigation orders. While most such challenges failed, at least two state supreme court rulings limited executive branch powers. The Wisconsin Supreme Court invalidated statewide stay-at-home and business closure orders in *Wisconsin Legislature v. Palm*, finding they exceeded the statutory authority of health department officials. In *In re Certified Questions*, the Michigan Supreme Court similarly concluded on nondelegation doctrine grounds that the Emergency Powers of the Governor Act — a broad emergency statute enacted in 1945 — did not authorize the governor to exercise emergency powers to respond to COVID-19, invalidating dozens of state orders. Michigan's state health department subsequently reinstated many of these order under different statutory authority. Inter-branch disputes at the state level over the extent of executive branch powers are likely to continue as at least 24 states have introduced legislation that would explicitly curtail public health powers (Barry-Jester et al., 2020), some drawing on model legislation from the libertarian-leaning American Legislative Exchange Council. States would benefit from creating substantive standards for how public health powers and emergency powers may be used to impose social distancing orders, but should not restrict the ability of executive branch officials from acting decisively to intervene when infectious disease pandemics require rapid intervention (Wiley, 2020).

Recommendations for Action

Federal government:

- Congress should appropriate significant, expanded, ongoing funding to support people who lose jobs or income due to state and local stay-at-home orders, business and school closures, and gathering restrictions so as to enable them to comply with these restrictions.
- Congress should enact legislation that strengthens and extends legal protections against eviction, mortgage foreclosure, utility shut off, discrimination, and employment loss due to stay-at-home orders, business and school closures, and gathering restrictions.
- Congress should appropriate significant, expanded, ongoing funding to support small businesses and school systems that were forced to close or reduce services due to COVID-19 mitigation orders.
- CDC should provide essential guidance to states, localities, and institutions about how to target and layer community mitigation strategies to best achieve significant reductions in COVID-19 transmission.

State governments:

- State legislatures should enact legislation creating substantive standards to guide the scope and authority of state officials to limit person-to-person interaction and impose closures, movement restrictions, gathering bans, and physical distancing requirements.
- Governors or other designated officials should promote social distancing to reduce the spread of COVID-19 through incentives, supportive programs, and legal protections that allow compliance with distancing guidance and reduce inequitable disparate impact of gathering restrictions and closures. If mandatory restrictions and closures are implemented, state officials should base these measures on the best available epidemiological and scientific evidence.
- Governors, through executive orders, and/or legislatures, through amending legislation should empower local governments to implement targeted and scientifically-appropriate interventions to respond to COVID-19, including the ability of local jurisdictions to impose more stringent limitations than the state on movement of individuals, gathering sizes, mask requirements, and closure of businesses, schools, and other activities.
- Governors, through executive orders, and/or legislatures, through amending extant housing, utilities, and employment laws, should extend protections against eviction, mortgage foreclosure, utility shut off, discrimination, and employment loss due to stay-at-home orders, business and school closures, and gathering restrictions.
- State and local governments should carefully draft social distancing orders to ensure that they are neutrally-worded and do not single out religious gatherings, and should include clear, scientifically-supported information justifying restrictions and explaining the scientific basis for differences in restrictions across categories of activities

Local governments:

- Local ordinances should allow for the imposition of targeted and scientifically-appropriate closure, movement, and physical distancing restrictions consistent with stopping the spread of COVID-19 in local communities.
- Mayors, through executive orders, and/or local councils, through amending extant housing, utilities, and employment laws, should extend protections against eviction, mortgage foreclosure, utility shut off, discrimination, and employment loss due to stay-at-home orders, business and school closures, and gathering restrictions.

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Surveillance, Privacy, and App Tracking

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SUMMARY. As the COVID-19 pandemic swept across the United States, American policymakers expressed optimism that digital contact tracing applications would mitigate the spread of the virus. Despite such hope, digital tracing tools have played virtually no role in reducing the transmission of COVID-19. This Chapter details the challenges faced and posed by digital contact tracing, exposes and criticizes its threats to stigmatized and marginalized populations, summarizes the lessons learned from our failed experiment with digital tracing in the context of COVID-19, and provides recommendations aimed at empowering the country to harness digital surveillance to stymie the spread of contagious disease when the next pandemic arrives.

Introduction

As explained in Volume I, Chapter 5, effective contact tracing demands several prerequisites. Contact tracing cannot succeed without accurate, widespread, and timely testing throughout the community. Unfortunately, the United States abdicated its duty to implement a coordinated national testing plan. The federal government consigned COVID-19 testing and tracing operations to the overwhelmed and often under-resourced states (Salomon & Reingold, 2020). The states, in turn, struggled during the first several months of the pandemic to develop standardized criteria as to what constitutes a COVID-19 "case," adequately test their constituents, and timely return test results. As various regions of the country witnessed viral surges over the summer and fall of 2020, these testing problems escalated, and over-stretched state public health officials were compelled to either scale back or abandon traditional contact tracing (Woodward, 2020). Questions about the accuracy of the tests that the U.S. Food and Drug Administration (FDA) authorized for use through its national public health emergency powers exacerbated the states' testing woes.

Contact tracing also requires honest participation from individuals who have been exposed to the disease, which is catalyzed by trust between the public and government contact tracers. Fear of misuse of the sensitive data collected by government officials has stymied efforts to track, trace, and contain the spread of the SARS-CoV-2 virus in the United States. Marginalized groups that have been disparately impacted by the virus and historically targeted by law enforcement and other surveillance agencies are concerned that police and immigration authorities will exploit contact tracing data to their detriment. Political polarization and social media propaganda have further eroded distrust in public health officials. As the 2020 winter holidays approached, the country's COVID-19 case count exceeded 200,000 a day and the United States witnessed record hospitalizations and deaths. However, a vocal minority of Americans, inclusive of various elected officials, continues to subscribe to the theory that the virus is a hoax and refuses to comply with basic transmission prevention tactics (Enriquez, 2021).

These obstacles to traditional contact tracing motivated policymakers to look to digital contact tracing applications to contain the spread of COVID-19. Digital surveillance tools are enticing because they are faster and less resource intensive than traditional track and trace methods. They nonetheless suffer notable drawbacks. First, digital exposure notification platforms are likely to generate both false negatives and false positives due to the nature and limits of their underlying technology. Second, the collection, storage, and aggregation of sensitive health and location data by digital applications raises novel privacy issues that the American health data privacy legal regime is ill-equipped to manage. Third, digital platforms exclude vulnerable individuals who are at high-risk of COVID-19 exposure but do not have access to the technology and data plans necessary to participate in mobile tracing. Finally, and like traditional contact tracing, digital contact tracing applications cannot effectively reduce viral spread without adequate community testing and public trust in both the government and the private companies that develop the platforms sufficient to motivate their widespread use. These issues that attend to digital contact tracing have colluded to minimize their use and effectiveness in the United States to date. For additional information on surveillance, privacy, and app tracking, please see Chapter 5 in *Assessing Legal Responses to COVID-19: Volume I*.

Updates

Since the publication of the first volume of this playbook, digital contact tracing has remained a persistent and unwavering failure. Perhaps because we are primed to believe that technology will rescue us, there was significant optimism that Big Tech's development and release of a decentralized framework for contact tracing applications in April 2020 would be a game changer in the fight against COVID-19. As it turns out, that optimism was tragically misplaced.

A year into the pandemic, "such apps have made slow progress across the country, hampered by sluggish and uncoordinated development, distrust of technology companies, and inadequate advertising budgets and messaging campaigns" (de la Garza, 2020). Recent reports indicate that only 18 states have adopted digital contact tracing applications and, in those states, only one in 14 residents have uploaded and utilized the technology (Mello, Jr., 2020). Connecticut currently stands as the most successful digital application uptake state in the nation, with just a 20% adoption rate (Mello, Jr., 2020). While traditional contact tracing has fared somewhat better than its digital counterparts, it also has faced considerable resistance. More than half of Americans who have become infected with COVID-19 have refused to cooperate with contact tracers (Lewis, 2020).

At the pandemic's inception, there also was hope that the United States would update its fragmented and inadequate health data privacy regime to bolster user privacy and, thereby, instill public trust in digital tracing applications. At least three bills that sought to regulate the use of contact tracking data, including the bipartisan Exposure Notification Privacy Act, were introduced in the Senate. None of that proposed legislation, however, gained traction in Congress. To be fair, the enactment of a federal privacy law that protects the sensitive health data collected by digital applications would not solve all the problems that have stymied the success of digital contact tracing. Federal action on this front, however, is long overdue. Moreover, protection of such individual health and location data is likely to benefit members of marginalized communities who are most likely to be subject to punitive state action, have suffered disproportionately during the pandemic due to systemic disparities in the health care delivery system, and are the subject of the next section of this Chapter.

Equity

The data overwhelmingly demonstrate that COVID-19 has disparately impacted various groups that have experienced historical stigma, discrimination, and abuse, including racial and ethnic minorities, individuals with disfavored health care conditions and criminal statues, and older Americans. Pandemic-related inequitable health outcomes are attributable to, among other things, structural racism, ableism, ageism, and long-standing economic inequality.

> "These systems affect health through a variety of pathways, including social deprivation from reduced access to employment, housing, and education; increased environmental exposures and targeted marketing of unhealthy substances; inadequate access to health care; physical injury and psychological trauma resulting from state-sanctioned violence such as police brutality and chronic exposure to discrimination; and diminished participation in healthy behaviors or increased participation in unhealthy behaviors as coping mechanisms." (Egede, 2020).

Digital contact tracing poses specific risks to these same populations. Communicable disease epidemics generally trigger widespread fear and the spread of insidious misinformation that unfairly blames marginalized groups for spread of the contagion. As early as the mid-1300s, white Europeans blamed Jewish people for transmission of the bubonic plague throughout the continent (McNeil, Jr., 2009). Americans scapegoated Haitian immigrants and sexual minorities as responsible for HIV transmission in the 1980s (Cohen, 2007). The same fate attended to Mexican Americans during the 2009 swine flu outbreak, West Africans during the 2014 Ebola epidemic, and, of course, Chinese Americans during the COVID-19 pandemic (Lee, 2020). These attacks on marginalized groups during public health emergencies incentivizes them to avoid data collection due to fear of law enforcement dragnets and other punitive measures.

American policymakers have made little effort to quell such targeting of stigmatized groups during the pandemic. In the face of widespread outbreaks of COVID-19 in U.S. meatpacking plants, which rely heavily on immigrant and racial minority labor, government officials placed the blame for viral transmission not at the feet of the employers who maintain non-hygienic and cramped work conditions, but on the immigrant workers who must endure those unsafe work environments (Stella, 2020). Meatpacking plants have long been subject to immigration sweeps by federal authorities. It is irrational to expect groups at heightened risk of criminalization, detention, and deportation to use digital tracking tools. That result, however, is counterproductive because an environment that motivates disease surveillance avoidance exacerbates the potential for poor public health outcomes for these workers and their families and heightens the risk of undetected viral spread throughout the community. In fact, Singapore experienced a surge of COVID-19 cases in the spring of 2020 linked to migrant workers living in cramped, dormitory-style quarters that the country's otherwise robust contract tracing system had entirely overlooked (Ratcliffe, 2020).

Older people also have been disparately impacted by COVID-19 and are incentivized to avoid digital scrutiny. As legal scholars have pointed out, the lives of older Americans have been devalued and viewed as expendable throughout the pandemic (Kohn, 2020). The residents of nursing homes and other overcrowded congregate care settings have been the victims of more than half of the COVID-19 fatalities across numerous states due to lack of government regulation. Older Americans may be motivated to opt out of digital data collection platforms due to fear of placement in such a viral incubator or at the bottom of a hospital triage list.

Other stigmatized individuals at high risk for COVID-19 infection who have been subject to criminalization and heightened surveillance because of their status, including sex workers, individuals with substance use disorder, people with HIV, sexual minorities, people who are homeless, individuals with disabilities, and people who are criminal justice-involved, may also be weary of digital tracking due to the possibility that public health authorities will share their data with the police or other government regulators. It is difficult to argue that such concerns are misplaced. The United States does not have in place a health data privacy statute that proscribes public health officials from sharing digital contact tracing data with law enforcement agencies.

It warrants emphasis that promises from public health agencies that they will safeguard such data from law enforcement notwithstanding their lack of legal obligation to do so are insufficient. During the summer of 2020, Singapore instigated widespread use of its digital TraceTogether application by expressly ensuring its citizens that the collected data would be used exclusively for contact tracing. In early January 2021, however, Singapore reneged on that promise by announcing that "[t]he Singapore Police Force is empowered … to obtain any data, including TraceTogether data, for criminal investigations" (Wamsley, 2021). Even assuming that the United States had laws and policies in place that addressed these law enforcement surveillance concerns, a significant subset of stigmatized and marginalized individuals would nonetheless be excluded from participating in digital contact tracing because they lack access to an adequate mobile device or data plan.

Lessons Learned

There are at least three lessons that can be gleaned from America's failure to deploy contact tracing in a manner sufficient to stymie the spread of COVID-19.

First, contact tracing cannot succeed without a robust and coordinated public health infrastructure. Before the next pandemic arrives, the United States needs to develop a federal plan that provides resources and funding to enable states to implement widespread, accurate, and timely testing, stand up a public health contact tracing workforce that is adequate to meet the challenge presented, and distribute the technological tools to at-risk populations to empower these groups to participate in digital public health surveillance. The federal government also should facilitate the creation of a digital tracking application for national adoption and use. The use of heterogenous digital tracing application across jurisdictions makes it difficult for those platforms to identify individuals who have been infected by COVID-19 and their contacts.

Second, the United States needs to enact a comprehensive health data privacy law that protects user privacy and, thereby, encourages the mass adoption of digital contact tracing applications during a public health emergency. Such legislation should ensure user privacy by minimizing data collection, permitting the deletion and correction of data, extending to users a privacy right of action, and complying with international data security best practices. It should also respect user autonomy, assure informed, voluntary consent, prohibit discrimination and the dissemination of collected information to non-public health authorities, prescribe the commercial use of collected data, proscribe the sharing of collected data with non-public health government entities, mandate government transparency, and include a sunset provision.

Finally, government officials need to carefully cultivate the trust of the American public generally, and stigmatized and marginalized populations specifically. The enactment of a comprehensive health data privacy law will further this cause, but is not enough. Federal and state policymakers can enhance public trust by embracing the threshold human rights principles of transparency and accountability and expressly combatting misinformation (Davis, 2020). The United States also must adopt public health emergency responses that protect marginalized groups from discrimination and ensure equal access to information, social services and supports, and health care. As the World Health Organization (WHO) has warned, a country's failure to pay "explicit attention to the needs and vulnerabilities faced by [marginalized and stigmatized] groups subjects them to higher risk of infection and undermines the broader [public health emergency] response" (WHO, 2020).

Recommendations for Action

Federal government:

- Congress should enact a statute that safeguards individuals from the risks that attend to digital contact tracing applications that, at the minimum, ensures user privacy; assures informed, voluntary participation; respects user autonomy; prohibits discrimination and the dissemination of collected information to non-public health authorities; proscribes the commercial use of collected data, mandates government transparency and accuracy, guarantees data security; includes a sunset provision; and extends a private right of action to users.
- In coordination with Congress, the executive branch of the federal government should develop and implement a national response that provides states with the resources and funding to implement accurate, fast, and widespread testing and stand up a robust and adequate contact tracing workforce.
- The executive branch should also adopt a single, well-designed contact tracing application that is user friendly, assists rather than undermines traditional track and trace efforts, and is compliant with the federal legislation outlined above.

State governments:

- In the absence of federal action to facilitate appropriate use of technology in pandemic control, states should enact a statute that safeguards individuals from the risks that attend to digital COVID-19 contact tracing applications and has the same features as the federal legislation previously described.
- To ensure that contract tracing apps and processes do not reflect bias or infringe upon civil liberties and human rights, state governments should ensure that contact tracing applications neither (1) disparately burden individuals on the basis of race, ethnicity, nationality, sex, religion, immigration status, LGBTQ status, or disability nor (2) document information that implicates users' civil liberties or human rights.
- State health authorities should provide no-cost cellular phones and data packages to individuals who wish to participate but do not have the resources to obtain the underlying technology, devices, and data plans.
- State health authorities should incorporate the use of traditional contact tracers with local connections to vulnerable communities rather than solely rely on automated surveillance to ensure the inclusion of individuals who do not have access to smartphone technology and/or otherwise distrust digital surveillance.

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Improving Data Collection and Management

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SUMMARY. Data are fundamental to good public health policies and their implementation. However, the lifecycle of public health data (collection, analysis, and distribution) in response to COVID-19 was flawed. Public health data suffered from politicization, a lack of centralized leadership, and substandard governance. These flaws must be quickly corrected. That rebuilding process should also seek to improve disease surveillance by leveraging syndromic surveillance, genomic surveillance, and digital epidemiology. Priority must also be given to addressing inequity by improving the amount and quality of sociodemographic data. As well as improving the quality of the data we collect, we must do more to make the data available to the parties that require it, presented in a form that maximizes its utility. Finally, our existing or novel institutions must find the appropriate balance between access and privacy.

Introduction

Sound public health policy and practice are evidence-based, driven by data that determine appropriate responses. For example, real-time information about who has a disease and where they live can help target interventions and resources, and provide valuable information about how a disease spreads within a population. When the data are inaccurate or incomplete, however, disease control measures suffer.

Many of the errors and missteps involving data collection and management during the first year of the COVID-19 pandemic in the United States were the product of politicization and inadequate leadership. Other data problems occurred even before data could be collected because public health agencies could not satisfactorily implement traditional contact tracing and digital app-based surveillance. There have also been sharp differences in the availability of testing for low-income and communities of color compared to more affluent areas home to largely insured, white people, further skewing the data collected and obscuring an unequal disease burden (Kim et al., 2020).

The pandemic exposed fundamental structural and data management flaws and the country's lack of an effective public health data system. Specifically, the United States lacks a unified structure for data gathering, management, and dissemination. But the errors that hindered pandemic response, such as politicization, lack of centralized leadership, and substandard data governance, also highlight a path forward. Improvement requires a uniform implementation of better models of disease surveillance and a concerted effort to identify and address inequity through targeted data collection. But, even the best data have limited utility if not rapidly available to decision-makers. The distribution of useful data, be it more granular or in the aggregate, will require tailored data governance depending in significant part on both the types of data in a dataset and on its intended end-users. Deep datasets containing sensitive and potentially personally identifiable information may require a data trust. However, for the quick dissemination of aggregate data, like for pandemic dashboards, too much infrastructure can be a hindrance. We begin by considering the impediments to effective data collection, management, and dissemination in the current pandemic. We then turn to how we can improve data collection and distribution. We end with our recommendations for the future.

Problems Identified during COVID-19

Three major, often overlapping data problems are politicization, a lack of centralized leadership, and defects in data management policies.

Politicization

During the first year of the pandemic, access to COVID-related data, like numbers of positive tests, of available hospital beds, and deaths, felt like a zero-sum game. Increasingly, motivated individuals weaponized data to cast actors, entities, and environments in favorable or unfavorable lights, and sway public opinion. Instrumentalizing data in this manner occurred at all levels of government, facilitated by a systemic lack of transparency.

Federally, there was considerable dislocation of the traditional data responsibilities of the Department of Health and Human Services (HHS), the Centers for Disease Control (CDC), and the White House. Specifically, reports surfaced of active interference by political

appointees in the publication of even "untouchable" data sources such as the CDC's *Morbidity and Mortality Weekly Report*. One of the many examples was the White House's insistence that officials delete language on the dangers of singing from the CDC's guidance on the reopening of churches in May 2020. Further, even after the CDC had upgraded its hospital tracking system, HHS took over the process, installing a private contractor to perform the data collection and tracking, severely undermining hospital compliance and data accuracy (Bandler et al., 2020). Federal actors similarly compromised data dissemination. For example, in December 2020, the White House Coronavirus Task Force stopped sending its tailored data and recommendations to each state on a proactive basis (Klein, 2020).

Similar stories played out in some states, typically when their governors sought to minimize the risks of COVID-19 and justify more lenient public health mitigation strategies. For example, in Florida, Governor Ron DeSantis reportedly fired the Department of Health's data dashboard manager after she initially refused to delete records showing positive cases at a time when the governor was arguing for reopening the state. Subsequently, the manager set up an independent dashboard providing granular data about Florida's cases and deaths (the COVID Monitor).

Lack of Centralized Leadership

COVID-19 has exposed shortcomings in the federated model of public health data management. The CDC has not asserted a strong leadership role in data collection, standards, reporting, and dissemination, and the states have taken divergent paths (Davenport et al., 2020). As a result, the country lacks a national standard for the reporting of COVID-19 test data. For example, states differ as to whether they report PCR tests, antigen tests, or both. States also have made frequent changes in the manner and frequency with which they report data. There are major differences in the mechanics of how different data or data from different sources are reported. For instance, some laboratory test data are first reported to state and local authorities before being passed on to the CDC. Other data are sent directly to CDC, while hospital laboratories report directly to HHS. These data problems resurfaced during the initial months of the vaccine rollout amid reports of serious flaws in the interoperability of federal databases such as Operation Warp Speed's Tiberius and CDC's VTrckS.

Because of delays in implementing reliable state and CDC dashboards, increasingly reliance has been placed on dashboards curated by media organizations such as the *Washington Post* or research institutions such as the Institute for Health Metrics and Evaluation. Additional, non-governmental tools have appeared to track effective reproduction rates (Rt.live, 2021) and predict the risks associated with various events and activities (mycovidrisk).

Substandard Data Governance

Data governance encapsulates collection standards, quality, integrity, and security of data during its lifecycle. One report concluded, "Unlike many other countries such as Germany, Senegal, South Korea, and Uganda, the United States does not have standard, national data on the virus and its control. The [United States] also lacks standards for state-, county-, and city-level public reporting of this life-and-death information" (Prevent Epidemics, 2020).

This approach to data governance is the product of dangerous levels of fragmentation across multiple dimensions. The most obvious is across administrative institutions, with responsibilities split among federal, state, and local agencies. Outside of the public arena, fragmentation occurs among private entities, often driven by proprietary interests that prevent data sharing between actors.

Relatively early in the pandemic, researchers recognized that data lacked granularity about key sociodemographic variables (Krieger et al., 2020), particularly race and ethnicity. There was also chronic underreporting (as low as 10%) of asymptomatic infections in the first months of the pandemic (Perkins et al., 2020). There is still no data-informed national plan to direct vaccines to neighborhoods bearing the largest burden of disease.

Beyond substance, COVID-19 exposed flaws in public health data processes. Too much data is captured in or transmitted in analog form (such as by fax). As cases surged during the winter months of 2020, health departments were often overwhelmed by the volume and logistics of processing testing data, the majority of which was not delivered digitally (Pearlstein & Moser, 2020). The resulting delay inhibited timely and targeted interventions.

COVID-19 data governance is overdue. Questions about indicators, such as whether "confirmed cases" include "presumptive positive cases" require standardized answers. Data are also fragmented by type or purpose. For example, demographic, racial and ethnic, clinical, and research data are viewed as distinct. Finally, like many aspects of health care, effective and efficient public health responses require collaboration and coordination between diverse groups, including providers, laboratories, and public health agencies. An individual may interact with the system at any of these points, and the ability to draw inferences requires connecting the dots. Improving data and data sources ultimately also requires a long-term investment in interoperability.

Improving COVID-19 Data

As noted above, fast and accurate data are critical for an effective and tailored public health response to a pandemic. However, data-driven interventions are only useful if the data underlying their design are reliable, high quality, and timely available. Several data categories should be part of mandatory pandemic reporting and made available to the public. This includes expanded surveillance approaches and data that help answer the who, what, when, where, and how of disease burden and spread. Tracking and addressing health disparities should be incorporated by design, with standardized reporting requirements for demographic information, congregate living, and secondary pandemic impacts like suicide and substance dependency.

Improving Disease Surveillance

While case counts are a key data point in pandemic response, they may lag behind broad community spread due to delays in test results and the onset of symptoms prompting an individual to seek

testing occurring after a patient is initially contagious. However, surveillance can identify community spread before it is indicated by clinical tests and hospitalization — a point by which early interventions are less effective. As a result, both biological and digital surveillance will be critical data sources for avoiding future waves of infection.

Biological Surveillance. Syndromic surveillance is a cornerstone of public health activity. It has long helped monitor flu, flu-like illnesses, and even potential bioterror attacks. Other indicators, particularly monitoring virus levels in sewage, are particularly useful for SARS-CoV-2. Research has shown sewage surveillance provides notice of community spread in advance of both hospitalizations and test result reports (Peccia et al., 2020). However, the lead time can vary depending on the speed with which localities can process and report test results (Peccia et al., 2020). These forms of surveillance take on increased importance in light of insufficient and inconsistent access to traditional tests and may provide enough early notice to slow community spread before cases overwhelm health care and public health systems.

Genomic surveillance has also been the key to understanding how COVID-19 has spread nationally and internationally. More specifically, understanding how and where outbreaks occurred in Germany and Washington State suggests that "intensive, community-level respiratory virus surveillance architectures" and genomic analysis are of particular value in reacting to future viruses (Worobey et al., 2020). Genomic surveillance is also essential for understanding mutations to the virus over time, helping identify potential changes in virulence and infectiousness. Reports suggest that the United States lags behind other countries such as the United Kingdom in collecting and analyzing virus samples.

Digital Epidemiology. Beyond the formal medical and public health infrastructure, digital epidemiology can improve detection and analysis. Digital epidemiology is a form of public health surveillance based on diverse data sources collected for non-public health purposes, such as mobile phone location data. Surveillance of internet searches and online activity can also predict an outbreak before more traditional mechanisms (Ginsberg et al., 2009). Other innovative forms of surveillance have proven particularly promising for the COVID-19 pandemic, both online and on the ground. Artificial intelligence, such as the BlueDot algorithm, famously identified early in the pandemic in December 2019, several days before the World Health Organization's (WHO) announcement, by analyzing online activity.

Unlike more traditional public health surveillance, digital epidemiology presents unique challenges. Obstacles include privacy and access to proprietary data (Tarkoma et al., 2020). Scholars have argued that the benefits of disease forecasting or modeling, and sophisticated contact tracing may need to override individuals' privacy interests. However, this should only occur when the alternatives — such as lockdowns — are worse. There should also be a responsible, transparent oversight process with broad representation from all stakeholders (Mello & Wang, 2020).

Addressing Inequity through Improved Data Collection

In addition to where the disease is spreading, it is critical to understand who bears the burden of disease and where and how they contract it. However, the collection of data on variables like race, ethnicity, income, and housing, or food insecurity has not been prioritized. By the end of 2020, only a handful of states reported COVID-19 testing data by race, limiting policymakers' abilities to equitably allocate resources like testing, education, and support. The impact of COVID-19 on people with disabilities was also sorely lacking, in part due to the lack of accessibility of tests and testing centers and in part due to how data were collected (Reed et al., 2020). For example, drive-through testing sites exclude individuals who do not drive. Similar problems arose with vaccine distribution with many states failing to collect race and ethnicity data notwithstanding a CDC mandate.

It is also critical to understand disease distribution. Contagious diseases take the most significant toll on those who live in close proximity to others, such as in long-term care facilities, prisons, and detention centers. Even though these living conditions are most vulnerable to spread of COVID-19, states inconsistently collect and report data on cases, deaths, and locations, obscuring the burden's true extent. Similar data collection deficiencies have hindered our understanding of the disease burden by occupation, including health care workers and employees in high-risk industries such as food processing.

Collecting and reporting these data are necessary for rapid pandemic response and contribute to the long-term understanding of the effects of that response on the population as a whole. For example, while nonpharmaceutical interventions like social distancing, isolation, and quarantine are essential tools to combat COVID-19, they also fracture social networks and support systems. Exacerbating this sudden loss of human connection is an environment of economic uncertainty and increased barriers to care (Reger et al., 2020). Social isolation is associated with worse health outcomes generally (Holt-Lunstad, 2017) and may lead to increases in cases of preventable death, like suicide (Reger et al., 2020). However, establishing these connections between secondary outcomes and pandemic interventions requires more and better data.

While data collection and reporting efforts by the media and other private actors are laudable, they are insufficient. Uniform policies and standards are sorely needed to capture these data to understand the burden of disease and to target limited resources to where they can have optimal impact. To do so requires a coordinated response, including a centralized, trusted agency in charge of data collection and evidence-based policy recommendations (Davenport et al., 2020). Some data can and should be collected, stored, and reported only in the aggregate. Some data must be more granular and identifiable to be useful. These datasets present different risks and challenges, and governance must be tailored to meet those needs.

Improving Data Distribution

An effective public health response requires that the right people can quickly access reliable information to make informed decisions. The United States botched its COVID-19 response in part because of serious missteps not only regarding data collection and management, but also its distribution. In addition to improving the quality of the data collected, we must ensure the data and derived information — once collected — are both secure and readily available to the parties that require them.

Both scientists and laypeople find dashboards, interactive online public health tools that provide community members with pandemic-related information in a given geographic area particularly useful. The CDC currently maintains a federal dashboard of data submitted to the agency (COVID-19 Module Data Dashboard). Other, extant dashboards provide data regarding states (e.g., Washington State Department of Health), counties (e.g., Harris County Public Health), nursing homes (AARP Public Policy Institute), and universities (e.g., Indiana University).

Pandemic dashboards should have a stated purpose — to provide reliable up-to-date, local, COVID-19-related information — and clear uniform policies about how they collect, manage, and protect their data. Best practices should be followed, and dashboard curators should work to standardize data presentations, for example whether to present data on a linear or logarithmic scale. The goal of pandemic dashboards is to provide citizens with reliable, up-to-date information about the pandemic in their area. Facilitating quick, easy access to accurate dashboard data is particularly important for older and other high-risk or vulnerable individuals so that they can make informed decisions.

The entities charged with warehousing data must strike the right balance between facilitating swift, straightforward data access to the proper stakeholders with ensuring privacy and security for sensitive information. One potentially useful model would be to establish a "data trust." Data trusts gained popularity in the United Kingdom as a means for facilitating data sharing while protecting the rights of data sources. A data trust has five key elements: (1) compliance with all relevant legal standards in the given jurisdiction related to data collection, distribution, and management; (2) clear data governance structures; (3) well-defined data management processes and policies; (4) required trainings for data users; and (5) public and stakeholder engagement (Paprica et al., 2020).

In the wake of the pandemic, as the United States reconsiders the level of independence required for important agencies such as the CDC and Food and Drug Administration (FDA), consideration should also be given to establishing a public health data trust as an independent federal agency, potentially named the Federal Public Data Agency (PDA). The PDA would be charged with rulemaking related to data standards, governance, and protection.

Conclusion

Politicization, lack of centralized leadership, and substandard data governance hindered initial responses to the COVID-19 pandemic, but they need not remain stumbling blocks. Improving pandemic response requires an intentional approach to data collection on both a macro and micro scale. Broader surveillance—in the traditional biomedical and public health sense as well as its novel, digital forms—can help policymakers stay ahead of the curve, obviating the need for controversial and disruptive control measures. Detailed, uniform data collection on key demographic variables can help decision-makers target limited resources intentionally to alleviate disparities in disease burden. But these approaches involve varying levels of risk and require different types of governance.

Ultimately, any sound data governance and distribution policy will depend in significant part on both the type of data in a dataset and on its intended end users. A rich dataset that includes comprehensive and potentially identifiable information requires more policies and safeguards than a pandemic dashboard that communicates only a single form of aggregated data. While the former is of use to researchers and public health authorities, the latter targets the general public. Data security and preventing unauthorized secondary use is important for potentially revealing datasets in the hands of sophisticated parties that might include the government and private companies. By contrast, ease of access is crucial when the dataset is limited, and the anticipated user is an ordinary citizen seeking to make an informed decision in real-time. Going forward, we must be careful to develop clear, transparent, flexible data governance structures tailored both to the kinds of data being collected and to the desired end users of that information.

The Biden administration clearly recognizes the country's data challenges and one of the incoming president's first executive orders ordered a sweeping review of the public health data infrastructure. At the federal level there must be one national agency charged with data collection. That agency must set the data standards for tests, cases, deaths, and sociodemographic data. The agency and its leadership must also "foster a data-driven culture" for future public health challenges (Davenport et al., 2020). A system cannot respond effectively to inequities in the absence of data. Data regarding race, ethnicity, income, and housing or food insecurity must be included in data sets and in analyses.

At the state level, all dashboards should adopt similar user interfaces and provide access to similar levels of granular data on a timely (daily) basis, including the 15 essential indicators. State dashboards also should follow best practices such as preferring rates over counts, smoothing data over time, "clearly identifying the intended audience, prioritizing key measures, having a clear organization and layout, presenting information to inform on health equity, updating information daily, and clearly labeling data and graphics" (Prevent Epidemics, 2020).

Recommendations for Action

Federal government:

- The federal government should designate a single federal agency or data trust in charge of public health data with clear and transparent communications with state and local public health agencies to build trust.
- The federal government should charge that agency with establishing accountability and overseeing enforcement for inappropriate data use.
- Federal and state governments working together should improve disease surveillance by dramatically increasing syndromic surveillance, genomic surveillance, and digital epidemiology.
- The federal government should publish clear and transparent policies and processes based on scientific best practices for collecting, maintaining, and disseminating data.
- The federal government should standardize data types, collection and transmittal models through legislation, regulations, model statutes, or professional guidelines.
- The federal government should prioritize the collection of sociodemographic data particularly as it impacts disparities and health equity.
- The federal government and Congress should work with industry and other developers to ensure that the technologies used by the government adhere to the highest possible privacy and security standards.

State governments:

- States should adhere to existing laws, regulations, and best practices at both the federal and state levels for collecting, maintaining, and disseminating data.
- States should standardize state-, county-, and city-level public reporting using data standards consistent with federal standards.
- States should comply with CDC mandates on the collection of race and ethnicity data during vaccine distribution.
- States should create streamlined and transparent processes for disseminating up-to-date, actionable data (such as data dashboards) to citizens.
- States should engage citizens by making data readily accessible for public use (e.g., pandemic dashboards), educate the public regarding new research or developments, and solicit and respond to feedback regarding these resources.

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Lessons from the 2020 Election Cycle

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SUMMARY. While the COVID-19 pandemic brought uncertainty during the primaries, states learned from those early contests and put measures in place to ensure voter access and safety while protecting the integrity of the elections process. These efforts were successful – voter turnout in the 2020 General Election broke records, with 66.7% of eligible voters participating in the election, the highest turnout since 1900. This turnout also resulted in success for a number of public health measures, success that was facilitated in part by state efforts to expand options available to voters, including expanded absentee ballot eligibility, extended voter registration deadlines, and a push for early and absentee voting. Success was also due to strong community organizing and the efforts of private individuals and businesses to ensure that the election was adequately staffed and resourced in the absence of additional federal funding. While some states have made or are making permanent changes to facilitate voter participation, and despite the record turnout and reports that this election was the most secure in American history, other states want to roll back changes made to elections policy during the pandemic and restrict voter access. The courts also seem to support restricting voting rights protections that conflict with state legislative decisions, and public health and elections officials experienced threats to their safety due to tensions over the pandemic and the outcome of the election that remain high. The Biden administration, Congress, and state governments must prioritize taking action to protect the right to vote, facilitate voter participation, and ensure the continued safety and security of future elections.

Introduction

The 2020 election cycle, like 2020 itself, has been described as unprecedented, and in many ways it was. There was record participation by the voting eligible population across voting methods in the primaries and in the November general election. States adapted elections administration to ensure the health and safety of voters even as information about the transmission and prevention of COVID-19 continued to evolve and officials debated the most effective public health interventions. The elections were also a victory for public health, both in terms of conducting safe elections (with few reports of COVID-19 infection related to in-person voting), and in terms of advancing health equity by enacting laws that increased voter participation and otherwise addressed the conditions that can create more equitable health outcomes for people of color and other historically marginalized populations.

While states made changes to expand ballot access, most states already have pro-voter laws in place for everything from automatic, same-day, and online voter registration, to no-excuse absentee voting and early voting options. These options exist in states with Democratic or Republican trifectas (where one party controls the executive branch and both chambers of the legislature) and in states with split governance structures. COVID-19 expanded the options available, and exposed voters to what it is like to vote in an election when the government makes it easier to vote. Voters also experienced a relatively smooth election despite inadequate resources and continued voter suppression efforts in some states, thanks in large part to community mobilization efforts, election protection, and the efforts of private individuals and businesses to ensure adequate elections resources. Going forward, it will be necessary to preserve and protect changes made during the 2020 election cycle that facilitated both voting and public health.

Looking Back at Preparations for the General Election

In August 2020, it was clear what needed to happen in November to ensure a successful election in the midst of a pandemic — voters needed access to different voting options and information about ways to vote safely and stay healthy. The primaries showed that elections officials could anticipate long lines and high turnout on Election Day, as well as continued record levels of mail-in and absentee ballots. It was clear that a new generation of poll workers would need to be recruited and that polling places would need to accommodate large numbers of voters in a way that was accessible and allowed for COVID-19 health and safety protocols to be enforced. These things all happened, albeit with

significant variation across states. Early voting was expanded, voter registration deadlines were extended, poll workers were successfully recruited, polling locations were successfully modified or established, and there were broad-based voter education campaigns to emphasize both the importance of voting and ways to create a safe voting plan. There were also successful efforts to address voter issues that disproportionately impact voters of color, such as preventing voter purges in Indiana and Wisconsin, and organized efforts to cure absentee ballots, which have a higher rate of rejection for voters of color, low-income voters, and young voters (Nichols et al., 2020).

Three of the biggest concerns leading up to the general election were the shortage of poll workers, limitations on polling places, and adequate funding. Organizations like More than a Vote and Power the Polls helped to successfully recruit more than 40,000 poll workers across the United States, and More than a Vote also teamed up with elections officials to allow sporting arenas to be used as early voting sites, drop box locations, and vote centers (NBA, 2020). States must now make these changes permanent by updating state law to expand poll worker eligibility; increase incentives for poll workers like improved compensation; and set standards for polling place closures and consolidation that ensure that voters will still have meaningful access.

Some states took these steps in 2020 by, for example, setting quotas for the number of open polling places, and lowering age restrictions and eliminating residency requirements for poll workers. Notably, Massachusetts enacted legislation that, although temporary, required election commissioners to consider whether polling place changes would have a disparate impact based on race, national origin, disability, income, or age (An Act Relative to Voting Options in Response to COVID-19, 2020). This may serve as a model for one way that states may respond to polling place closure in a post-*Shelby* environment where the preclearance provisions of the Voting Rights Act of 1965 for jurisdictions with a history of discrimination in voting no longer apply (*Shelby County v. Holder*, 2013).

This is not to suggest that all changes during this election cycle were pro-voter. Some state legislatures enacted more restrictive measures and courts limited election policy changes imposed due to the pandemic. In addition, funding was inadequate across the board, but is critical for ensuring health and safety by resourcing poll workers, polling locations, education campaigns, machines and equipment, cleaning supplies, and training. One analysis pre-pandemic illustrated unfunded security needs like voting equipment and software updates, cybersecurity improvements, and post-election audits (Howard et al., 2019). While the CARES Act allocated $400 million to the states for these kinds of costs, it was estimated that $4 billion would be needed to ensure election security in 2020, and the deficit was largely made up by donations of money, PPE, space (like sporting arenas), and other supplies by individuals, businesses, and non-profits (Córdova McCadney et al., 2020). Congress must make a commitment to sustained federal funding for elections to promote voter access and election security.

A Push for Electoral Reform

State legislatures enacted a number of election reforms in response to COVID-19, some permanent, and some temporary. These reforms largely facilitated voting by making changes to mail or absentee voting processes, and also addressed concerns raised during the primaries about the number of poll workers and polling locations (discussed above).

Among the more significant changes was the expansion of absentee voting eligibility. Of the 16 states in which voters must have an excuse to request an absentee ballot, 12 expanded eligibility by allowing COVID-19 as an excuse, allowing illness or disability generally, or eliminating the need for an excuse. States also mailed absentee ballots or ballot requests to all registered voters, provided pre-paid postage for all mail ballots, extended ballot receipt deadlines, and changed ballot processing time frames (NCSL, 2020a). While all states require valid signatures on absentee or mail-in ballots, 32 states require signature matching verification, and only 18 states require notice to voters of missing or discrepant signatures with an opportunity to cure (NCSL, 2020b). In response to COVID-19, five states expanded or enacted a notice or notice and cure policy (Michigan, New Jersey, New York, North Carolina, and Virginia). Notably, all of these changes occurred in both Democratic, Republican, and split governments and nearly all of these changes were temporary.

Many of these changes were made under existing election day emergency authority or authority granted to the governor under emergency conditions. Now, states are revisiting both the changes made to elections administration and the authority to make them. Kentucky is perhaps the best example of this. Under Section 39A.100 of the Kentucky Revised Statutes, the governor has emergency power to modify an election and, upon the recommendation of the Secretary of State, to declare by executive order a different time, place, or manner for holding elections during a declared state of emergency. For the 2020 election, Kentucky expanded absentee ballot eligibility due to COVID-19 concerns and created an online absentee ballot request process; expanded early voting; required vote centers in counties that consolidated polling places; enabled online ballot tracking; and allowed ballots postmarked by November 3, 2020, and received by November 6, 2020, to be counted. Now, in the 2021 legislative session, the legislature has passed a bill that removes the governor's authority to change the manner of elections by executive order (although time or place can still be changed) and the executive order itself cannot be changed except by action of the General Assembly (S.B.1, 2021). Kentucky made a number of changes that facilitated voter turnout and ensured voter safety and election security during 2020, and efforts to limit the authority to adapt elections for public health emergencies in future elections are a step in the wrong direction.

Kentucky is not alone — the Georgia General Assembly will be considering bills to eliminate no-excuse absentee voting (which has been in place since 2005), the use of ballot drop boxes, and unsolicited absentee ballot application mailings, as well as a

ban on the use of early voting buses and requiring a photo ID for absentee voting (usually only required for in-person voting). These are all measures that will make voting harder, and that will disproportionately impact people who have historically experienced limited access to the polls, due to age, disability, access issues, and racist voter suppression efforts.

The bottom line is that changes made to elections administration due to COVID-19 were a necessary response to ensure a safe and secure election, but they are also changes that present opportunities for long-term improvements that will ensure robust participation in future elections. State legislatures must ensure that legislation that is introduced addresses legitimate questions about the process of administering an election rather than ways to suppress the opposition or alternative views.

The Role of the Courts

Hundreds of lawsuits involving election administration were filed in the lead-up to the general election, and another 54 lawsuits were filed post-election in an attempt to overturn the election results. Prior to the election, it was noted that courts may be reticent to change election policy close to an election in consideration of the *Purcell* principle that courts should not change election procedures close to an election (*Purcell v. Gonzalez*, 2006). It was also recommended that courts reconsider their role and be more willing to apply the *Anderson-Burdick* test to balance the interests of the state against the burden on the right to vote to determine which measures are necessary to facilitate the right to vote while maintaining the integrity of the ballot (*Anderson v. Celebrezze*, 1983; *Burdick v. Takushi*, 1992). Indeed, both the *Purcell* principle and the *Anderson-Burdick* test played a key role in litigation, from reinstating witness requirements in South Carolina (*Andino v. Middleton*, 2020), to limiting ballot drop box sites in Texas (*Texas League of United Latin American Citizens v. Abbott*, 2020), and allowing an extended deadline for receipt of ballots to stay in place in North Carolina (*Moore v. Circosta*, 2020).

However, a more threatening legal theory took shape during the 2020 election cycle that the federal courts have a role to play in preventing state courts and other state actors from making changes to protect the vote under state law if those changes are inconsistent with the state legislature's actions (*Moore v. Circosta*, 2020; *Republican Party of Pennsylvania v. Boockvar*, 2020). This could potentially upend the Supreme Court's past decisions upholding the rights of states to enact election laws through a lawmaking process, including by ballot initaitive (See, e.g. *Arizona State Legislature v. Arizona Independent Redistricting Commission*, 2015), which held that the Elections Clause of the U.S. Constitution and 2 U.S.C. § 2a(c) permit the use of an independent commission to adopt congressional districts). A potential consequence is that other state laws governing the electoral process that were enacted through a lawmaking process (but not through the legislature itself) could be subject to challenge.

This theory was evidenced in the denouement to the flurry of post-election lawsuits in *Texas v. Pennsylvania*, with the Texas Attorney General arguing that four decisive states in the 2020 general election (Georgia, Michigan, Pennsylvania, and Wisconsin) used the COVID-19 pandemic to make unconstitutional changes to voting laws through non-legislative means (*Texas v. Pennsylvania*, 2020). While the Supreme Court declined to hear the case for lack of standing, some questions about the authority to make changes to election policy remain unresolved and without federal legislation, state level changes to federal elections processes will continue to be vulnerable to legal challenges. Ultimately, these disputes over executive or legislative authority to ease voting requirements became a fight over the legitimacy of the election, arguably contributing to the insurrection at the Capitol on January 6, 2021.

One way to avoid some of these disputes is for Congress to take action to set minimum federal elections standards that expand voting access and protect the right to vote. These minimum standards should include expanded voter registration, which continues to be one of the main barriers to voting, by establishing automatic, same-day, and online registration. Voters in record numbers also took advantage of absentee, mail-in and early voting during the pandemic as safe alternatives to Election Day voting, and any federal standards should permanently expand access to the ballot by establishing national no-excuse absentee voting, establishing a minimum nationwide early vote period, and preventing the purge of eligible voters from voter rolls. Changes states made due to the pandemic facilitated turnout, and it is necessary to make those changes permanent to ensure continued civic participation.

Other Concerns

As the pandemic has progressed and struggles continue across the United States — with high levels of unemployment, congressional stalemates over financial relief, misinformation and distrust about public health measures, and record cases, hospitalizations, and deaths — tensions among the public have escalated. Pre- and post-election, these tensions were inflamed by false claims about widespread voter fraud and challenges to elections policy in key states, undermining trust in the election outcome. This often resulted in violence or threats of violence against both public health and elections officials. States must enact or strengthen provisions to protect public officials, ensuring that there are penalties and mechanisms of enforcement.

Finally, the 2020 election cycle was also significant because it coincided with decennial census, the data from which determine legislative redistricting. New legislative and congressional maps are drawn by the state legislature or through redistricting commissions (or both), making the outcomes of the 2020 election critical for determining who controls the redistricting process. The maps drawn determine representation, and representation determines the distribution of resources and power and drives policy across the social determinants of health. State legislatures must take action to reduce or eliminate partisan gerrymandering to ensure equitable representation. Options include establishing independent redistricting commissions or using algorithms to create new districts using measures related to district compactness or other factors like political or geographical boundaries (for example, a town or city), or otherwise establishing objective criteria.

A Successful Election Cycle for Public Health

What did record turnout mean for public health and health equity? Economic measures that narrow the racial wealth gap and improve economic stability, like Medicaid expansion and minimum wage increases, were successful this year. Missouri and Oklahoma became the latest states to adopt Medicaid expansion by ballot measure, with expansion coverage expected to start by July 1, 2021 in both states. That leaves just 12 states that have not expanded Medicaid, despite the clear evidence that it has reduced racial disparities in health coverage and access to care in expansion states, a decision that largely impacts people of color, who comprise nearly 60% of the four million uninsured adults in non-expansion states (Cross-Call, 2020).

Florida became the latest state to approve an increase in its minimum wage by approving a ballot initiative to increase the minimum wage to $15 an hour by 2026. This follows on the heels of 24 states and 48 cities and counties that implemented minimum wage increases in 2020 (Lathrop, 2019). Popularity for economic measures like this has grown during the COVID-19 pandemic, and recent research has demonstrated that increasing the minimum wage decreases racial economic disparities (Derenoncourt et al., 2020). However, the federal minimum wage remains $7.25 an hour and wage preemption continues to disproportionately impact women and people of color amid reports of significant job losses for both groups during the pandemic.

Both of these economic initiatives are also significant because they may lead to better health, and better health leads to a more engaged electorate. Research shows a consistent association between voter participation and health conditions, with health and socioeconomic disparities linked to reduced voter turnout (Brown et al., 2020). People experiencing chronic health conditions or living with a disability are less likely to vote, as are people making less than $30,000 a year and people with a high school degree or less, who are disproportionately Black and Hispanic or Latino voters. By enacting laws that improve both health and socioeconomic conditions, states are likely to see improved voter turnout and the continued introduction and success of similar initiatives that address inequities.

Other significant public health victories in the 2020 election cycle include voter enfranchisement in California and Washington, DC; decriminalization of low-level drug possession in Oregon; the election of sheriffs who ran on eliminating contracts and/or cooperation with ICE; an increase in income tax on high earners in Arizona to fund public education; pre-school for all in Multnomah County, OR; increased taxes to pay for public transit in cities like Austin, Denver, Fairfax, San Antonio, and Seattle; paid medical and family sick leave in Colorado; and establishment or strengthening of police oversight boards in cities like Boston, Philadelphia, Pittsburgh, San Diego, and San Francisco. These are all initiatives that impact social conditions, education, access to opportunity, and economic stability and can have the effect of reducing disparities for people of color, immigrants, women, and other marginalized populations.

Participation in the voting process is one way to dismantle the laws and policies that create barriers to education, health, power, and economic opportunity by ensuring that elected officials better represent the electorate and have shared experiences with their constituents. One of the biggest lessons from the 2020 election cycle is that facilitating participation in democratic processes is one way to build power in communities, and post-election, it will be important to continue to facilitate participation, build civic infrastructure and promote civic education, and equip communities to organize on issues and hold elected officials accountable. Creating a more equitable future means investing in and building the capacity of communities year-round.

Recommendations for Action

All levels of government must take steps to protect democracy in order to make meaningful movement toward health and racial equity.

Federal government:

- The Biden administration should develop an infrastructure to include voices from the community in policy development and implementation.
- The Biden administration should invest in civic infrastructure and education.
- Congress should ensure sustained funding for elections administration.
- Congress should enact minimum elections standards including automatic, same day, and online voter registration; national no-excuse absentee voting; a minimum nationwide early vote period; and preventing the purge of eligible voters from voter rolls.

State governments:

State legislatures should:

- Eliminate felony disenfranchisement laws.
- Set fair standards for drawing electoral boundaries by creating independent redistricting commissions, using algorithms, and/or establishing objective criteria for districts that preserve communities of interest and ensure racial fairness, among other factors.
- Ensure protections for elections, public health, or other public officials.
- Update state law to expand poll worker eligibility; increase incentives for poll workers; and set standards for polling place closures and consolidation that ensure that voters will still have meaningful access.
- In the absence of federal standards, enact laws that facilitate voter access and protect the right to vote.

About the Author

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PART 2

Fulfilling Governmental Responsibility in a Federal System

Executive Decision Making for COVID-19: Incorporating Equity Considerations

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SUMMARY. Executive decision-making is the crux of using law to achieve public health objectives. But if the goal of executive decision-making is only to achieve immediate public health objectives, such as a rapid reduction in communicable disease, progress toward the important long-term objective of achieving health equity may suffer if vulnerable populations are left further behind. To the extent possible, the actions necessary to promote public health during a pandemic, such as stay-at-home orders and restrictions on businesses, should attempt to produce equitable results, or at least avoid exacerbating existing inequities. In this Chapter, we examine how governors and other state decision-makers have used their legal authority to mitigate the inequitable effects of COVID-19. We begin with an overview of the executive decision-making tool for public health officials that was introduced in Chapter 7 in Assessing Legal Responses to COVID-19: Volume I. Then we describe where considerations of equity fit into this model. Next, we briefly review how the eight states considered in Volume I, Chapter 7, have responded to the COVID-19 pandemic since July and examine their efforts to support vulnerable populations in their responses. In responding to a pandemic, we conclude that health officers first need to determine what options among potential actions are needed to protect the public's health. As much as possible, equity should be included in weighing the options and evaluating trade-offs.

Introduction

Chapter 7 in *Assessing Legal Responses to COVID-19: Volume I* focused on how public health officials exercise their professional judgment in working with elected officials to mitigate the spread of COVID-19. It explained the legal authority for COVID-19 stay-at-home orders, as well as political and judicial constraints on an executive's ability to take such action. It further analyzed eight states' responses to the COVID-19 pandemic, with particular attention paid to the role of politics and science in the decisions made. This Chapter adds new analysis and recommendations to the original chapter. It again focuses on how public health officials exercise their judgment in responding to COVID-19, but with a specific focus on health equity. It should be noted that the allocation of vaccines presents unique issues beyond the scope of this chapter. (For more information on the allocation of scarce medical resources, such as vaccines, see Chapter 24 in *Assessing Legal Responses to COVID-19: Volume I*.)

The Executive Decision-Making Tool

As discussed in Volume I, Chapter 7, executive decision-makers — public health officials, including governors acting to respond to the pandemic, and agencies — have considerable discretion under most state public health and emergency response codes in which their decisions must be made. To exercise its broad grant of authority, officials and agencies must ask three key questions: Can I? Must I? and Should I?

Can I? focuses on whether the public health official or agency has the legal authority to act, and if so, in what way. These actors' public health authority is based on the police power, which provides the authority for states to protect the public's welfare, safety, and health (*Jacobson v. Commonwealth of Massachusetts*, 1905).

Must I? asks whether there are legal requirements, including funding source directives, that mandate action and define how the public health official or agency must act. Usually, the official or agency has considerable discretion in deciding how to fulfill its obligations.

Should I? is a policy question requiring the official or agency to determine whether and how to exercise discretionary authority. Discretionary authority must be used reasonably and impartially, never in an arbitrary and capricious manner.

To meet the need for simple, step-by-step guidance to aid public health officials faced with these difficult decisions, the Public Health Executive Decision-Making Tool, also described in Volume I, Chapter 7, provides a template to support executive decision-making when confronting a public health threat (Chrysler et al., 2021). The tool outlines a clear approach for analyzing a public health threat as it unfolds and for documenting the decision-making process. As further expanded on in Volume I, Chapter 7, the tool's steps are to *assess the situation*, *evaluate the threat*, *discuss mitigation*, *assess the level of certainty*, and *communicate*.

In implementing this approach, executives have various health equity frameworks to use. For instance, the Network for Public Health Law has developed an approach that complements our Executive Decision-Making Tool (Network for Public Health Law, 2020). Another viable option is "An Equity Lens Tool for Health Departments" (Human Impact Partners, 2020).

Executive Decision-Making, Ethics, and Equity

When considering *Should I?*, executive decision-makers take into account many considerations, including politics and science. Whether the proposed action is ethical is also an important factor to consider in determining if the decision-maker should take a given public health action. Public health officials and agencies have an ethical obligation to ensure that they take into account the effects of their potential actions on vulnerable populations, such as low-income individuals, racial and ethnic minorities, and individuals with disabilities for which health and health care disparities exist (Artiga et al., 2020).

This consideration of ethics fits into the Executive Decision-Making Tool in both the *evaluate the threat* and the *discuss mitigation* steps. The potential disproportionate impact of the threat on vulnerable populations should be determined, as should the potential disproportionate impact of mitigation options on different populations.

In analyzing an action, equity considerations fall primarily under the public health ethics value of distributive justice. Distributive justice "requires that the risks, benefits, and burdens of public health action be fairly distributed, thus precluding the unjustified targeting of already socially vulnerable populations" (Gostin & Berkman, 2007). It requires the executive to "act to limit the extent to which the burden of disease falls unfairly upon the least advantaged and to ensure that the burden of interventions themselves are distributed equitably," as well as to ensure that public health benefits are allocated fairly (Gostin & Berkman, 2007).

Despite this ethical obligation, when urgent and immediate public health action is required, ensuring an equitable distribution of risks, benefits, and burdens may not be possible. First, an action that has an inequitable distribution of risks, benefits, and burdens may be required to avoid (further) endangering the public health. For example, in the context of COVID-19, stay-at-home and business- and school-closure orders may burden low-income individuals disproportionately, but not instituting such orders risks increased spread of COVID-19. Second, public health officials and agencies must sometimes choose between two options, each of which inequitably burdens different populations or that burdens the same populations in different ways. Continuing from the previous example, while stay-at-home and closure orders may burden certain populations, the increased spread of COVID-19 that would occur in the absence of these orders may itself have a disparate impact on the same — or other — vulnerable populations. Third, actions to ensure equitable distribution of benefits and burdens may not be legal, as they may violate the Equal Protection Clause, which requires equal treatment as distinct from equitable treatment. Because of this, a governor likely could not order the closure only of those businesses that could afford such closure.

For these reasons, while ethical considerations should be included in the process of executive decision-making, they cannot be expected to dictate results. Since the law can play a role in furthering equity, it will be important to conduct post-pandemic studies to determine whether and how the various COVID-19 orders addressed equity considerations.

Executive Decision-Making and Equity: COVID-19

In this section, we first provide a brief update on the COVID-19 response of each state considered in Volume I, Chapter 7 (Alabama, Arizona, Colorado, Florida, Maine, Michigan, Texas, and Wisconsin). We then focus on how these states have used their legal authority to address equity issues that have resulted from the COVID-19 pandemic.

Analysis

Response updates. As discussed in Volume I, Chapter 7, each of the aforementioned eight states issued emergency orders in March 2020 and, by the first week in April, had issued stay-at-home orders. Each state except Michigan (which is operating under a state health department epidemic order) is still operating under a governor-declared emergency (National Governors Association, 2020).

Since July, all eight states first experienced periods either of declining COVID-19 case rates followed by a period of relative case stability or of stability at relatively low case rates and then experienced a gradual but dramatic increase in cases (Allen, 2021). Most states responded to this increase, some more quickly than others, by mandating additional restrictions (see National Academy for State Health Policy, 2020). In some states, the governor imposed stricter measures, such as lowering gathering and occupancy limits (e.g., in Maine) or by placing stronger mitigation requirements on outdoor gatherings (Arizona). Some states' extant orders had built-in restrictions that triggered stricter measures when various thresholds were met, such as in Texas and Arizona. Colorado's governor instituted a new phased reopening system with such built-in restrictions.

However, two of the four states in which Republicans control both the executive and legislature have acted contrary to data indicating increasing COVID-19 cases (see National Academy for State Health Policy, 2020). Alabama's governor issued an order on November 5, 2020, removing occupancy limits for certain businesses and excepting certain businesses from social distancing requirements, despite a seven-day case average that had been overall increasing

since mid-October. Also in November, the governor of Florida extended his September order placing the state into phase three of the state's recovery plan. This action eliminated the restrictions from phases one and two and permitted all businesses to operate and restaurants to operate at least at 50% capacity regardless of local laws; Florida's seven-day case average had been increasing since mid-October.

Actions taken to promote equity. It is undeniable that COVID-19 has had devastating and disproportionate effects on racial and ethnic minorities and other vulnerable populations. It is equally undeniable that the pandemic has exacerbated existing health care inequities. For example, the widely used business closures and restrictions have especially affected low-wage workers who experienced high levels of job loss. As a consequence, many low-wage workers have been unable to afford adequate housing and food. School closures and virtual learning almost certainly have had a profound and negative effect on students who require more intensive or unique education services (American Public Health Association, 2018).

States can also take actions to help ameliorate some of these negative effects and to address disparities that are a factor of race or ethnicity. Of the eight states discussed above, the four states with Democratic governors have developed groups or programs focusing on equity issues in the context of COVID-19; additionally, the majority of the states have participated in at least one such program (National Governors Association, n.d.). Each of the states has also, to varying degrees, taken other actions to help further health equity.

Alabama

Alabama's executive branch participates in the Reskilling and Recovery Network, a program aimed at increasing workers' skills to help them obtain employment and addressing equity issues (National Governors Association, n.d.). Gov. Kay Ivey prevented enforcement of evictions and foreclosures due to nonpayment during her stay-at-home order, permitted release of certain individuals from county jails, permitted summonses and complaints instead of custodial arrests for certain offenses, and allocated CARES Act funding to provide internet access to low-income children for distance learning. The state health officer permitted in-person programs provided by boards of education for children of first responders, health care providers, and certain essential workers when in-person classes were otherwise prohibited. Alabama has also ensured that those unable to work as result of COVID-19 can file for unemployment benefits and expanded a program providing children with two free meals a day during the summer to the duration of school closures.

Arizona

The Arizona executive has been involved in equity-promoting projects, such as the Black Arizona COVID-19 Task Force and the Reskilling and Recovery Network. Gov. Doug Ducey has delayed enforcement of evictions if individuals meet certain COVID-19 related criteria: exempted from his stay-at-home order individuals who are homeless or whose homes are unsafe; required schools to provide on-site learning to students who need somewhere to go during the day; and included as essential operations organizations that provide social and charitable services for vulnerable populations and home-care services and day-care providers for essential workers.

Colorado

In April 2020, Colorado instituted the COVID-19 Health Equity Response Team in order to "focus specifically on tackling . . . inequities to prevent the gaps from widening and ultimately saving lives;" it also participates in the Reskilling and Recovery Network. Gov. Jared Polis has ordered limits on evictions, foreclosures, and public utility disconnection; expedited the processing of unemployment insurance claims; and provided stimulus payments to qualified individuals.

Florida

Florida Gov. Ron DeSantis has suspended laws providing causes of action for mortgage foreclosures, as well as for residential evictions related to non-payment of rent as a result of COVID-19; included as essential businesses those that provide services to vulnerable individuals, child-care providers for essential workers, and home-care providers; and allocated CARES Act funding for rent and mortgage assistance. The Department of Economic Opportunity suspended several requirements for eligibility for unemployment benefits. The Florida Department of Education, in its school reopening order, ordered school districts to work to identify students with IEPs and students who are English-language learners who may have regressed while schools were closed and to consider compensatory and/or additional services for them.

In spite of these actions, Florida has had some equity failures: it took five weeks for government leaders to conduct completely bilingual briefings, and a county commissioner whose district includes a majority-Hispanic ZIP code stated that "we had to fight to get [COVID-19] testing in that neighborhood" (Santich & Chen, 2020).

Maine

Maine instituted a COVID-19 Health Equity Improvement Initiative, in which the state reimburses community-based organizations in minority communities that work to educate on COVID-19 and its prevention in culturally sensitive ways and to provide services related to COVID-19. Gov. Janet Mills also suspended the limits on the timeframe in which children could stay in emergency or homeless children's shelters and expanded the age range of individuals who qualified to stay in such shelters, extended the statutory interest-free grace periods and repayment period for loans for employees whose income was reduced as a result of COVID-19, expanded the period of general assistance benefits and suspended the work-search requirement as a condition of receiving such benefits, implemented eviction protections, and implemented a rental relief program, providing rental assistance of up to $1,000 per month.

Michigan

Michigan Gov. Gretchen Whitmer created the Michigan Coronavirus Task Force on Racial Disparities to study COVID-19 racial

disparities, make recommendations to address racial and other disparities in the COVID-19 pandemic and other pandemics, and perform community and stakeholder outreach. She also ordered employer-provided migrant housing camps to take certain actions to help prevent COVID-19 in migrant and agricultural workers; expanded unemployment benefit eligibility; prohibited employers from firing or retaliating against individuals with COVID-19, symptoms of COVID-19, or potential exposure to COVID-19 who did not go to work during specified periods during their illness or quarantine; and ordered restoration of public water supply service to residences where such service had been terminated due to failure to pay bills. The state's department of health later continued migrant and agricultural worker protections; it also required the state to house and meet the basic needs of homeless individuals affected by COVID-19 and for individuals with unstable housing.

Texas

Texas participates in the Reskilling and Recovery Network. Gov. Greg Abbott included as essential services those that provide necessities and social services to needy individuals and waived, for COVID-19–related services, the health-care service fees that incarcerated individuals ordinarily have to pay. Other state agencies implemented rental and public utility assistance and eviction diversion programs. However, the governor prevented local jails from releasing inmates for non–health-related reasons, which was contemplated in an effort to reduce jail populations to prevent the spread of COVID-19, in a variety of circumstances. Further, Black state lawmakers have been pushing for actions to address inequities, for example, for the state to gather information on COVID-19 disparities, but one Black state representative said that "[i]t's like [myself, my colleagues, and people of color] don't exist" (Barragán, 2020).

Wisconsin

Wisconsin's Just Recovery for Racial Equity initiative was instituted to provide grants to community-based organizations and support COVID-19 response and recovery and resiliency building in communities of color. The state also is a member of the Reskilling and Recovery Network. Gov. Tony Evers has also banned evictions due to failure to pay and foreclosures and allocated CARES Act funding to a rental assistance program. State agencies ensured that the families of children who would have received free or reduced lunch at school received benefits during the time in which schools were closed, that the work requirement and monthly premiums for the state's Medicaid program for adults with disabilities who work or want to were removed; and that monthly premiums were also removed for children and childless adults who are enrolled in the state's health insurance program for low-income individuals.

Discussion

Just as states have varied widely in their COVID-19 responses, they have varied in their efforts to promote health equity during the pandemic. In some states, governors aggressively provided relief to vulnerable populations; in others, state agencies did more of the work. The states in our sample varied in the priority given to remedying inequity. Methods of promoting equity differ, ranging from providing direct monetary assistance to those in need to ensuring that the children of essential workers have a place to go while their parents work.

Public health science must always drive executive decision-making in mitigating a pandemic. The primary duty is to prevent the spread of disease. In addressing the immediate need to mitigate a disease outbreak, executive decision-makers should also take into account existing health disparities among vulnerable population groups. As the examination above shows, there are numerous ways in which states can take complementary actions to provide relief to those who bear a disproportionate share of the impact of such restrictions. They have an ethical duty to do so. In addition, some states have focused resources on racial and ethnic minorities who face worse outcomes from COVID-19 itself, while others, like Florida, may need to improve their efforts in this area. This type of action not only promotes equity; it can also help slow the spread of disease.

Resource constraints likely pose the biggest obstacle to providing relief to populations in need. In the case of COVID-19, the federal government provided states with inadequate funding to provide vulnerable populations all the assistance they need. States cannot depend solely on federal funds to ensure that their residents are not unjustly burdened by a pandemic and the state response to it — they must think creatively about what they can do during every step of their response to promote equity.

In responding to a pandemic, we conclude that health officers first need to determine what options among potential actions are needed to protect the public's health. As much as possible, equity should be included in weighing the options and evaluating trade-offs. For public health measures to be successful, basic needs should be met and people must be treated fairly vis-à-vis others. COVID-19 demonstrates the limits of achieving equity when only some people are sacrificing for the common good. Equity demands either that sacrifices are distributed fairly or that those who sacrifice are made whole. To address the equity challenge, it is crucial that health officers work with those who have access to the resources needed to address inequities created by or the measures used to control a pandemic.

Recommendations for Action

State and local governments:

- Governors should incorporate equity considerations into their decision-making and address the needs of vulnerable populations and instruct public health and other officials to do the same.
- States and localities should collect and analyze complete and accurate COVID-19 morbidity and mortality data by race, ethnicity, age, and socioeconomic status.
- Public health officials, when planning for public health emergencies, should include equity considerations as an essential concern and advocate that all parts of state and local government plan in advance actions they could take to help ameliorate inequitable effects arising from public health emergencies.
- Public health officials, when responding to public health emergencies, should consider how already-existing disparities may cause outcomes to be worse in certain populations and work to reduce this inequitable distribution of outcomes.
- After-action reports should examine how equity considerations can be incorporated into epidemic response policies and practices.

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Federalism in Pandemic Prevention and Response

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SUMMARY. An underfunded, uncoordinated patchwork of state-led interventions failed to protect the American people from the 2020 coronavirus pandemic and contributed to stark geographic, racial, ethnic, and socioeconomic disparities. In most cases, state, Tribal, and local governments are in the best position for on-the-ground implementation of community mitigation and medical countermeasures tailored to local conditions. But only the federal government has the inter-jurisdictional coordinating authority and deficit-spending ability necessary to support and harmonize public health activities and ensure equity during a nation-wide emergency. In 2020, the Trump administration failed to adopt clear guidelines for coordination among agencies and jurisdictions. Congress failed to provide adequate funding to ramp up federal, state, Tribal, and local public health infrastructure, to support the ability of businesses and households to comply with public health recommendations, and to protect disempowered workers and tenants. For the most part, the federal government left financially stressed, budget-constrained state governments to fend for themselves. In September 2020, the Centers for Disease Control and Prevention (CDC) took an important step to protect vulnerable renters by issuing an unprecedented nationwide eviction moratorium order, pushing the boundaries of the agency's authority. Legal challenges to the federal moratorium were rejected by two federal district courts. The resulting judicial opinions could pave the way for a more expansive federal role in direct regulation of businesses and individuals, but questions about administrability and enforceability remain. In 2021 and beyond, federal regulatory and legislative reforms could put equitable and effective pandemic response on firmer footing or, alternatively, erode preparedness for future emergencies.

Introduction

In our federalist system, authority and responsibility for protecting the public's health is shared between the federal government, Tribal governments (addressed in Chapter 12), and the states, which typically delegate some of their authority to local governments. The federal government is limited to the exercise of powers enumerated in the Constitution. In contrast, states have plenary power to safeguard the public's health, safety, and welfare, subject to constitutional constraints that protect individual rights. Supreme Court precedents have interpreted limited federal powers — including powers to regulate interstate commerce and to spend for the general welfare — broadly, however, making it possible for Congress to encroach upon domains of traditional state and local authority. When the federal government acts, it can preempt state and local law. Similarly, state governments typically have broad authority to preempt local law.

Although state governments bear primary responsibility for public health in our federalist system, pre-pandemic plans recognized that the federal government must play a key role in ensuring a nationally funded and coordinated response. In most cases, state, Tribal, and local governments are in the best position to provide on-the-ground implementation of community mitigation (e.g., quarantine and isolation, restrictions on businesses and personal movement, and mask wearing) and medical countermeasures (e.g., testing, treatment, and vaccination) tailored to local conditions. But only the federal government has the deficit-spending ability and inter-jurisdictional coordinating authority necessary to support and harmonize public health activities and ensure equity during a nation-wide emergency.

Recognizing the substantial resources and interstate and international coordinating authority an effective public health emergency response requires, Congress has granted the federal administration a wide range of authorities and resources that it may use to support states (Katz et al., 2017). Federal officials are authorized — but not legally obligated — to act: 1) to prevent the international or interstate spread of infection; and (2) in situations where state and local capacity is likely to be overwhelmed. These non-mandatory powers include authority to provide critical supplies and financial resources using existing federal funds. In some areas — including approval of laboratories, medical tests,

vaccines, and drugs — Congress has preempted state authority. In other areas — including travel restrictions and isolation and quarantine of individuals—federal and state authority overlap. With so many overlapping authorities and responsibilities, it is unsurprising that interjurisdictional finger pointing has marked nearly every major public health crisis in recent American history (Gostin & Wiley, 2016).

In 2020, the president, Department of Health and Human Services (HHS) Secretary, and other officials frequently blamed, rather than partnered with states. Federal agencies could have relied on programs created by Congress in the aftermath of the 2001 terror attacks, the 2003 SARS outbreak, the failed response to Hurricane Katrina, and amid concerns about the potential for an influenza pandemic to provide financial support for and clear communication to states and other stakeholders (Katz et al.,, 2017). In addition, planning and guidance documents created by past administrations should have equipped the Trump administration to coordinate response efforts at the national level. But these legislative authorizations and administrative plans did not impose legally binding obligations on executive branch officials. When federal officials failed to exercise the responsibilities preparedness plans assumed they would, there was no legal mechanism for affected stakeholders to seek court orders requiring them to do so. Congress has not issued clear directives to the administration mandating action in response to emergencies, even when state and local resources and authorities are overwhelmed.

For more information on federal-state conflicts over regulatory authorizations, business regulations, controls on personal movement, financial support, and coordination of supply chains in the first half of 2020, please see Chapter 8 in Assessing Legal Responses to COVID-19: Volume I. This follow-up Chapter briefly discusses the balance between federal and state authorities to secure equitable access to medical countermeasures (e.g., testing, treatment, and vaccination), and support community mitigation (e.g., quarantine and isolation, restrictions on businesses and personal movement, and mask wearing). It then offers an extended examination of the September 2020 CDC eviction moratorium order and two federal district court opinions declining to enjoin it. These decisions could lay the groundwork for a more active federal role in directly regulating businesses and individuals as part of pandemic response efforts — in the Biden administration and well into the future.

Federal Authority to Ensure Access to Medical Countermeasures

Throughout 2020, the Trump administration and Senate leadership repeatedly disclaimed federal responsibility for ensuring access to personal protective equipment, testing, treatment, and vaccination based on equitable and public health criteria. Federal statutes, including the Public Health Service Act and the Defense Production Act (see Chapter 24) provide authorities and resources the administration could have used to secure supply chains and provide guidance and surveillance capabilities to support state efforts. Congress and the Trump administration invested billions in federal funding to support development and purchase of new tests, vaccines, and treatments. After providing initial public health, health care, and stimulus funding in March 2020, Congress failed to act again for several months.

Even as state and local health departments issued increasingly urgent calls for resources to support widespread testing and to initiate planning and infrastructure development for an unprecedented vaccination campaign, Congress failed to respond (NACCHO, 2020). Investments to secure the "last mile" of distribution, which are critical to ensure equitable access to medical countermeasures and their effective deployment as public health tools, were delayed until late December. Amid reports of logistical failures that predictably marred the early months of the vaccination campaign, some governors blamed federal guidelines for the allocation of scarce vaccines that were based on public health goals and equity. Some abandoned federal guidelines and announced that they would open up access to vaccines for age-based groups that vastly exceed the number of doses available at the time. They did so without ensuring adequate resources and coordination to do so equitably or efficiently, resulting in distribution of scarce vaccines based on connections to private hospital systems that received initial doses and the ability to spend hours navigating unpredictable and inaccessible systems (Blackstock & Blackstock, 2021).

Federal Authority to Support Community Mitigation

In 2020, the Trump administration failed to adopt clear guidelines to coordinate community mitigation efforts across jurisdictions. Federalism constraints were a significant barrier to the uniform, nationwide "lockdown" restrictions and face covering requirements some commentators argue would have ensured a more effective response to the coronavirus pandemic. Proponents of very strict social distancing and face covering orders expressed concern about lack of national uniformity (Haffajee & Mello, 2020), but it is unlikely they would have approved of a federally-controlled response that resulted in nationally uniform, but lighter, restrictions or preemption of state and local face covering mandates. Along with separation of powers constraints, federalism constraints allowed state and local governments to adopt and maintain health measures the president clearly opposed. Regardless of whether tighter or looser restrictions and mandates would have been a better approach, inconsistent messaging from federal, state, Tribal, and local leaders about the goals of social distancing, the level of restrictions needed, and for how long may have eroded public cooperation and trust. Inconsistent federal messaging on face coverings certainly did.

Even more critically for equity, Congress failed to provide desperately needed funding to support the ability of businesses and households to comply with public health recommendations and legal protections for disempowered front-line workers and tenants at risk of eviction. Although social distancing strategies have focused primarily on restrictions on businesses and personal movement, supports to enable people to comply with public health recommendations are equally important. Federal efforts to provide financial support (e.g., stimulus payments, unemployment insurance, and rental assistance), legal protections (e.g., paid family, medical, and quarantine leave and a short-term extension of a federal eviction moratorium), and accommodations

(e.g., adapting federal school meal programs to allow pick-up service) to ensure that everyone is able to comply with social distancing restrictions and recommendations while minimizing secondary harms were spotty and inconsistent. Americans waited months between the March 2020 and December 2020 relief bills. Many state and local governments took steps to freeze evictions and utility shut-offs and provide nutrition support, but without more federal financial assistance, these efforts were largely stop-gaps.

Judicial Decisions Defining the Boundaries of Federal Authority to Regulate Businesses and Individuals

From the earliest days of the pandemic, commentators speculated about whether the Trump administration could issue nationwide public health orders like those implemented in many other countries — or, alternatively, whether he could interfere with state orders by loosening or lifting them. Under the Constitution, federal restrictions on business operations and personal movement or requirements to wear face coverings must be adopted as a valid exercise of federal powers enumerated in the Constitution. Power to regulate interstate commerce and impose conditions on the acceptance of federal funds would probably be sufficient to permit Congress to adopt uniform social distancing restrictions and face covering requirements. But without a more specific delegation than the Public Health Service Act currently provides, most legal experts assumed the president did not have authority to interfere with state social distancing or face covering orders. The combination of federalism constraints and uncertain statutory authority has caused both the Trump and Biden administrations to be appropriately hesitant to embrace a strong federal role in ordering business restrictions or mask requirements.

The primary source of authority for federal executive action to mandate and support social distancing and face covering is Section 361(a) of the Public Health Services Act (PHSA), 42 U.S.C. § 264. The key text, which dates to the original PHSA of 1944, authorizes the HHS Secretary "to make and enforce such regulations as in his judgment are 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." The statute refers to the Surgeon General, subject to the approval of the HHS Secretary, but following administrative reorganizations, it is now read to refer to the secretary directly, who has in turn delegated authority to the CDC Director and U.S. Food and Drug Administration (FDA) Administrator. A CDC regulation interpreting this authority states:

Whenever the Director of the Centers for Disease Control and Prevention determines that the measures taken by health authorities of any State or possession (including political subdivisions thereof) are insufficient to prevent the spread of any of the communicable diseases from such State or possession to any other State or possession, he/she may take such measures to prevent such spread of the diseases as he/she deems reasonably necessary, including inspection, fumigation, disinfection, sanitation, pest extermination, and destruction of animals or articles believed to be sources of infection (42 C.F.R. § 70.2).

A September 2020 CDC order halting evictions through the end of the calendar year pushed the boundaries that experts previously assumed applied to federal executive authority (CDC, 2020; Wiley, 2020). This was the agency's first attempt to test the outer limits of its authority under Section 361 and Section 70.2. The order temporarily halted evictions of covered tenants from residential properties. Covered tenants were required to make a sworn declaration that they met income-based eligibility requirements and had exhausted available government assistance programs and that eviction would lead to homelessness living in "close quarters in a new congregate or shared living setting," among other requirements. Interest groups argued that while the order could buy time for at-risk tenants by delaying evictions, it fell short of the rent-relief and other financial assistance needed to address the housing crisis and associated exacerbation of disease transmission (see Anderson, 2020).

The CDC eviction order was challenged by landlords on the grounds that it exceeded the agency's statutory and regulatory authority, was not a proper exercise of federal power to regulate interstate commerce, inappropriately infringed on matters of state governance, and violated the landlords' constitutionally protected rights.

In 2020, two federal district courts issued opinions refusing to enjoin the CDC eviction order: the Northern District of Georgia in *Brown v. Azar*, 2020 (Oct. 29, 2020) and the Western District of Louisiana in *Chambless Enterprises v. Redfield*, 2020 (Dec. 22, 2020). Both courts easily disposed of the individual rights challenges. They also readily rejected the federalism challenges, based on precedents interpreting the interstate commerce power broadly.

Both courts offered an extended analysis of the statutory and regulatory interpretation issue, describing the outer boundaries of the federal agencies authority to regulate businesses (and, by implication, individuals who are not reasonably suspected of being infected or exposed).

The plaintiff-landlords argued that the courts should rely on canons of statutory construction that essentially boil down to a directive that the courts should assume Congress did not intend to authorize such a sweeping agency order unless the legislature did so with "a high degree of clarity" (*Chambless v. Redfield*, 2020). The two federal district courts analyzed each of these canons of construction in detail and ultimately found that "the plain text of the statute is unambiguous and evinces a legislative determination to defer to the 'judgment' of public health authorities about what measures they deem 'necessary' to prevent contagion. Congress's use of the phrase 'such regulations as in his judgment are necessary' shows that it intended to defer to agency expertise" (*Chambless v. Redfield*, 2020).

These two decisions could have far-reaching implications for the federal government's role in responding to the coronavirus pandemic and for federal communicable disease control powers more broadly. As Ilya Somin argued, "If Congress can delegate the

power to suppress virtually any activity of any kind, so long as the CDC claims that doing so is 'reasonably necessary' to reduce the spread of disease, it is hard to see how any meaningful limits on delegation would remain" (Somin, 2020).

There are, however, meaningful constraints imposed by Section 361 and Section 70.2. Unlike state and local leaders, federal officials are limited to the exercise of powers enumerated in the Constitution. Public health — particularly community mitigation efforts that rely on controlled movement and business restrictions to slow the spread of infection — is primarily governed at the state level. The typical federal role — which has largely been abdicated in this crisis — is to finance, support, guide, and inform state and local efforts. Section 361's emphasis on preventing the inter-state spread of infection reflects the gap-filling role the federal administration is intended to play. Section 70.2 of the CDC's regulations implementing Section 361 arguably narrows the federal role further, by making CDC authority contingent upon a finding that state and local efforts are "insufficient to prevent the spread of communicable diseases" across state and territorial borders.

CDC could further strengthen regulatory guardrails for compulsory measures intended to increase social distance and mandate use of personal protective equipment (such as face masks). Individually enforceable regulatory rights to hearings, such as those adopted in the CDC's 2017 amendments to federal regulations governing individually targeted quarantine and isolation orders are not a good fit for orders applicable to the general population. But Congress could amend the PHSA (or CDC could revise Section 70.2) to require the CDC Director to articulate the scientific basis for any guidance or orders issued pursuant to Section 361, including the nexus between the order and the interstate or international spread of disease, and the insufficiency of state and local efforts.

In the early days of the Biden administration, CDC used Section 361 to renew the CDC eviction order and impose a mask requirement for public transit. Notably, the transit mask order applies to modes of public transit that are entirely intra-state. The order may be challenged, but it is probably justifiable as a valid exercise of the federal power to regulate the channels and instrumentalities of interstate commerce and economic activities with substantial effects on interstate commerce. Whether the new administration will issue additional CDC orders imposing nation-wide, federally-imposed restrictions on personal movement and businesses to increase social distance and mandate face covering remains to be seen.

There are reasons to be wary of expanding the federal role in social distancing restrictions and face covering mandates. For one, local conditions vary from place to place and time to time throughout the course of a pandemic. Nationally uniform rules may not always be appropriate or desirable. For another, enforcement options are more limited at the federal level. Section 368(a) of the PHSA, 42 U.S.C. § 271(a), makes any violation of a regulation issued under Section 361 a crime; 42 CFR § 70.18 provides that violations are subject to steep fines and jail time. CDC's eviction and transit mask orders have relied on these provisions to indicate that harsh criminal penalties may be available. But enforcement mechanisms and the administrability of criminal penalties for a violation of broadly applicable CDC disease control orders remain unclear. Many state and local governments have used licensing-based penalties, such as smaller fines and suspension of business licenses, to enforce restrictions without relying heavily on criminalization and community policing. But federal agencies have little involvement in licensing and thus fewer levers available to incentivize compliance without resorting to criminalization. Federal financial support is crucial, but federal restrictions should be adopted with caution.

Recommendations for Action

Federal government:

- To ensure that the federal executive branch provides adequate financial support, addresses shortages, bottlenecks, and interstate competition for scarce supplies in future public health emergencies, Congress should replace permissive language in the Public Health Services Act with mandatory language to direct the Department of Health and Human Services to support state and local efforts by acquiring and distributing supplies via the Strategic National Stockpile.
- CDC should amend 42 C.F.R. § 70.2, to add transparency and accountability mechanisms requiring the secretary of HHS and the CDC director to articulate the scientific basis for any guidance or orders issued pursuant to the authority provided by the Public Health Service Act to control the spread of communicable disease, including the nexus between the order and the interstate or international spread of disease, and the insufficiency of state and local efforts.

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Preemption, Public Health, and Equity in the Time of COVID-19

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SUMMARY. Preemption is a legal doctrine that allows a higher level of government to limit or eliminate the power of a lower level of government to regulate a specific issue. As governments seek to address the myriad health, social, and economic consequences of COVID-19, an effective response requires coordination between state and local governments. Unfortunately, for many localities, the misuse of state preemption over the last decade has increased state and local government friction and weakened or abolished local governments' ability to adopt the health- and equity-promoting policies necessary to respond to and recover from this crisis. The broad misuse of preemption has left localities without the legal authority and policy tools needed to respond to the pandemic. Existing state preemption of paid sick leave, municipal broadband, and equitable housing policies, for example, forced local governments to start from behind. Moreover, many state executive orders and legislative responses to COVID-19 outlawed or are attempting to outlaw local efforts to enact stronger policies to protect the health and wellbeing of communities. And, preemption in the time of COVID-19 has worsened the health and economic inequities affecting people of color, low-wage workers, and women. Conflict between state and local governments has cost lives, delayed effective responses, and created confusion that continues to undermine public health efforts. The new coronavirus pandemic has made it clear that the overwhelming majority of state preemption occurring today harms public health efforts and worsens health inequities. The crisis also has underscored the need to reform and rebalance the relationship between states and local governments.

Introduction

Preemption is a legal doctrine that allows a higher level of government to limit or eliminate the power of a lower level of government to regulate a specific issue. Under the Constitution, federal law takes precedence over state and local law. Similarly, if a local law conflicts with a state law, the state law generally takes precedence. Depending on the type of preemption, lower level governments may be prevented from passing any laws affecting a particular policy realm or from passing certain types of laws affecting that realm.

Historically, preemption was used to ensure uniform statewide regulation, protect against conflicts between state and local governments, and sometimes advance wellbeing and equity. Indeed, preemption is not inherently adversarial to public health, equity, or good governance. Targeted preemption has the power to promote fairness and equity when state or local governments enact harmful policies or when they fail to address systemic injustices (Carr et al., 2020). For example, states such as California and Oregon have preempted certain local laws to facilitate the production of more affordable housing.

However, in many state legislatures, preemption increasingly has been weaponized by well-organized anti-regulatory advocates to prevent local communities from enacting laws that could reduce inequities and enhance wellbeing. Rather than attempt to balance or integrate the interests of state and local governments, "new preemption" is characterized as "sweeping state laws that clearly, intentionally, extensively, and at times punitively bar local efforts to address a host of local problems" (Briffault, 2018).

New preemption is often driven by corporations, trade associations, and conservatives opposed to local regulation across a broad range of policies. These include policies related to minimum wage; commercial tobacco control; paid sick days; safe, stable, and affordable housing; and other laws that would directly benefit individuals such as low-wage workers, people of color, and women (Partnership for Working Families, 2019; Huizar & Lathrop, 2019; Policy Surveillance Program, 2020). The combined impact of existing preemption laws and preemption laws enacted in the context of COVID-19 has undermined local governments' ability to effectively and equitably respond to the health, social, and economic consequences of the pandemic.

Effects of Preemption Laws Enacted Prior to COVID-19

Since 2011, states have increasingly preempted local authority across a broad and growing range of economic, civil rights, health, and environmental issues. The consequence of this misuse of state preemption is that many local governments lack the authority to enact laws and policies that can reduce health inequities among underserved populations, such as people of color, low-wage workers, and women — the same communities disproportionately harmed by the health and economic effects of COVID-19 (Carr et al., 2020; APM Research Lab, 2020).

Widespread preemption during the years leading up to the pandemic meant that municipalities could not, for example, immediately adopt paid sick leave policies to cover health care and other frontline workers. State-level emergency paid sick leave policies were required in states such as Indiana, Michigan, and North Carolina, among others (A Better Balance, 2020). In some states, including Florida and Tennessee, advocates requested that their governors suspend paid sick leave preemption so local governments could do more to protect residents.

Similarly, the pandemic's economic fallout worsened the existing housing crisis. Some local and state governments implemented eviction and foreclosure moratoria to keep residents from losing their homes. In some states, however, existing state preemption interfered with local governments' ability to adopt such policies (Local Solutions Support Center, n.d.). In Wisconsin, the Tenant Resource Center explained that local governments are "prevented from doing so due to state preemption." In contrast, California's governor issued an executive order to suspend state preemption of certain types of local eviction protections.

Figure 11.1

POLICY AREAS AFFECTED BY NEW PREEMPTION	
New state preemption laws have restricted or eliminated local authority to protect public health and equity across a range of issues, including:	
Economic Policies Minimum wage, paid sick time, wage theft, local hire, pensions, fair scheduling	**Public Health and Safety Laws** Gun safety, tobacco and e-cigarette policies, food labeling, sugary drink regulation
Local Zoning and Affordable Housing Inclusionary zoning, rent control, source-of-income nondiscrimination, short-term rentals	**Technology** Broadband, 5G, self-driving vehicles
Civil Rights Antidiscrimination, sanctuary cities, immigration	**Environmental Protection** Factory farming, plastic bags, styrofoam, energy benchmarking, fracking

With Americans forced to work, learn, and find medical treatment online, COVID-19 has also made fast, affordable, and reliable internet access essential. But in many states, preemption prohibits local governments from building or expanding access to municipal broadband — limitations that disproportionately hurt people of color, low income, and rural residents even before the pandemic (Community Networks, n.d.). Many states — including those with municipal broadband preemption — have acted to increase internet access and decrease costs. For example, the Nebraska Public Service Commission allocated funds to reimburse internet providers for providing service to low income families. Although some state action to expand broadband access may have been necessary irrespective of municipal broadband preemption, the inability of local governments to proactively address broadband access in the years leading up to the pandemic amplified the scope and urgency of state intervention.

Preemption in COVID-19 Executive Orders

Many state COVID-19 executive orders have included express preemption that has hampered localities' ability to protect their communities. State executive orders, including stay-at-home orders, have included three forms of preemption: floor, ceiling, and vacuum.

In some states, governors issued statewide stay-at-home orders but allowed local governments to implement additional restrictions based on local conditions. By establishing a **regulatory floor**, the executive orders did not prevent local governments from taking additional action to protect their residents. For example, Louisiana's governor allowed New Orleans to lift and impose restrictions based on changing local conditions, recognizing the unique concerns of the state's largest city, which is also home to the state's largest Black population.

Unfortunately, this collaborative approach is not the norm. In many states — Arizona, Florida, Georgia, Mississippi, South Carolina, Tennessee, Texas, and West Virginia, among others — the statewide stay-at-home orders established a **regulatory ceiling**. That is, the statewide orders prevented local governments from imposing stricter requirements than the state. For example, Arizona's governor issued an executive order prohibiting any county, city, or town from issuing any order or regulation "restricting persons from leaving their home due to the COVID-19 public health emergency." Similarly, the Texas attorney general successfully sued to stop El Paso County, Travis County, Austin, and other local governments from imposing shutdown, masking, and curfew orders that were more restrictive than state orders.

Some states, such as Iowa, did not have any statewide stay-at-home orders in effect but still preempted local governments from issuing their own orders, creating a **regulatory vacuum**. For example, although the Iowa governor did not issue a statewide stay-at-home order, she and the state attorney general informed local officials that cities and counties lack the authority to close businesses or order people to stay at home.

As cases of COVID-19 surge, local governments have demanded the authority to respond with mandatory mask-wearing and other

safety precautions, intensifying state-local government conflict. Georgia Governor Brian Kemp sued Atlanta Mayor Keisha Lance Bottoms when she enacted a mandatory masking rule, preventing the rule from going into effect. In Florida, Governor Ron DeSantis ultimately allowed localities to issue mask mandates, but his executive orders continue to prohibit local governments from actually enforcing them or collecting fines for other COVID-related violations. Nebraska's governor warned local governments they would not receive federal COVID-19 funds if they imposed masking or other local rules.

In California, the opposite has happened. After California's governor issued a statewide mandatory masking order, several local law enforcement agencies announced they would not enforce the order. The mayor of Nevada City encouraged residents to defy the mandate to "prevent all of us from slipping down the nasty slope of tyranny." California localities that do not comply with minimum statewide health and safety standards will be ineligible for $2.5 billion in state aid for local governments; however, unlike Nebraska, California does not intend to penalize localities that adopt more restrictive local orders. Governors in Illinois, New Mexico, North Carolina, and Pennsylvania, among other states, have also threatened to cut funding or take legal action against defiant localities.

Preemption and the Recovery

The misuse of state preemption is also undermining local governments' ability to effectively and equitably address long-term recovery from COVID-19. Areas of state and local conflict with the potential to impede recovery include preemption of local fiscal authority, worker safety laws, tenant and mortgage holder protections, emergency powers, stay-at-home orders, mandatory masking orders, vaccination policies, sanctuary city protections, and elections. For example, 48 states limit local fiscal authority to raise and spend revenue — known as tax and expenditure limits (TELs) — which will impede the economic recovery of localities with significant consequences for people who rely on local public health and safety, education, and other services (Policy Surveillance Program, 2020). As a result of these restrictions on tax revenues, cities are now cutting services when the community needs them most, laying off and furloughing employees, and mothballing capital projects, which has consequences for local employment, business contracts, and overall investment in the economy and community.

In the aftermath of the 2007–2008 housing crisis, moreover, local fiscal distress led to municipal bankruptcies, the imposition of state emergency managers, and other state takeovers of local governments. As the water crisis in Flint, MI, attests, this kind of fallout can have dire consequences. Similar state interventions in the recovery ahead appear likely given the impact of the current downturn on local finances.

Housing, which has been a critical issue in acute responses to the COVID-19 emergency, is likely to remain an issue during recovery. Evictions and foreclosures disproportionately affect people of color, women, and low-wage workers. Although local governments are considering a range of tenant protections, such protections are among the many equitable housing policies preempted by states across the country, including rent regulation, inclusionary zoning, and source-of-income antidiscrimination (Local Solutions Support Center, n.d.).

Conflict over masking mandates, stay at home orders, vaccination, and business shutdowns also have resulted in new efforts to more permanently restrict emergency and public health powers: legislation introduced in at least 24 states seeks to limit the powers of public health officials. Many of these bills align with model legislation from the anti-regulatory American Legislative Exchange Council (ALEC). Although many of these proposed and enacted laws target both state and local authority, others include restrictions specific to local governments and local health officials. Moreover, because many public health decisions made and actions taken are at the local level, restrictions that do not solely target local authority may nevertheless have a disproportionate effect on local governments. If successful, these efforts to weaken public health powers will undermine not only responses to COVID-19, but also future efforts to prevent and respond to future public health threats, including new pandemics.

Effects on Racial, Socioeconomic, and Other Preexisting Inequities

As local governments develop innovative solutions to advance health equity and improve health and wellbeing, preemption most often serves to impede such efforts (Carr et al., 2020). These impediments have substantial consequences generally and within the context of COVID-19 specifically.

For example, given the stark racial and socioeconomic disparities in health outcomes related to COVID-19 — disparities directly attributable to racism and other forms of structural discrimination — state preemption of local preventive measures to reduce the spread of COVID-19, such as more protective local stay-at-home orders, is almost certain to worsen existing health inequities. This is particularly true when health status, including the existence of preexisting conditions that worsen negative outcomes related to COVID-19, is intimately tied to ZIP code, and can vary substantially over short distances. Moreover, states governments have even interfered with local efforts intended to counter COVID-19-related health inequities — Texas, for example, threatened to reduce Dallas' vaccine supply if local leaders did not rescind a plan to prioritize vaccinations in predominately communities of color.

State preemption laws affecting the social and structural determinants of health are also likely to create or worsen inequities. Governments at all levels have adopted emergency policies, including tenant protections, broadband access, paid sick and family leave, and economic supports like increased unemployment and nutrition assistance benefits. However, once the current pandemic subsides and these temporary policies expire, widespread state preemption means that the same underserved populations unfairly harmed by COVID-19 will once again be unable to take action to protect their health and economic security. From an equity perspective, the misuse of state preemption to block local health and equity-promoting policies makes it harder for individuals and communities to care for themselves and their families. Indeed, because many states

prohibit localities from enacting policies across a broad array of issues, millions of people—many of them from communities of color and low income communities—have been excluded from the opportunities and health benefits that those laws would provide (Partnership for Working Families, 2019; Huizar & Lathrop, 2019).

Similarly, state TELs that constrain the means by which local governments may raise revenues are also likely to undermine health and equity. The inability to raise revenue means that localities may lack the resources to provide the services and supports necessary to counter the health and economic effects of COVID-19. Because COVID-19 has disproportionately affected underserved communities, these gaps in services and supports will further reinforce such inequities. Moreover, state TELs force local governments to turn to alternative forms of revenue generation, which often means fines and fees. Data show that people of color and residents who have low income are disproportionately affected by fees and fines for low-level offenses. "These fines and fees can affect credit scores, plunge families into debt, result in loss of a driver's license, or lead to incarceration" — all outcomes that can negatively affect health (Watts & Michel, 2020).

Used appropriately, targeted preemption has the power to promote fairness and equity. For example, federal civil rights laws passed during the 1960s to counter government-sanctioned discrimination by states and localities were, in fact, preemption laws that established minimum nationwide protections. Those laws exemplify the use of preemption to advance equity and extend opportunity to people who were previously excluded (Carr et al., 2020).

In the COVID-19 context, targeted state preemption can help protect public health and advance health equity when local laws, government officials, or community opposition stand in the way of an effective response — by blocking testing centers or quarantine sites, for instance, or by lifting stay-at-home orders before state health officials determine it is safe to do so. Similarly, statewide stay-at-home orders can establish baseline protections for all residents while allowing local governments to impose additional restrictions that address variations in local conditions.

The COVID-19 emergency reminds us that the overwhelming majority of preemption laws sweeping the country represent a coordinated assault on the political power of communities of color, low-income workers, and other marginalized groups. But it is critical to recognize that inequities result from decisions at all levels of government. As the country responds to and recovers from the COVID-19 pandemic, governments and public health decisionmakers must seek to repair and rebalance the relationship between state and local governments by combating the misuse of preemption while leveraging its potential to create and protect safety and opportunity for all. It is also critical to evaluate how state and federal preemption has affected both equitable responses to COVID-19 and ongoing recovery efforts, especially effects on underserved communities such as people of color, persons with low incomes, and women.

Federal Preemption

Under the Constitution's "Supremacy Clause," federal law takes precedence over lower-level laws. The federal government has "limited powers," meaning it only has those powers enumerated by the Constitution such as to tax, spend, and regulate interstate commerce. Despite these limitations, the federal government has the authority to make and enforce important laws related to public health and equity, including the ability to enact laws that preempt some or all state and local laws on particular issues. Indeed, while federal preemption has garnered less attention in recent years, it nevertheless remains a relevant consideration for responding to and recovering from the COVID-19 pandemic.

As with state preemption, federal preemption can sometimes advance public health and equity. The federal government, for example, exercised its authority under the Public Readiness and Emergency Preparedness (PREP) Act to preempt state and local laws restricting the ability of pharmacists to order and administer COVID-19 tests (U.S. Dept. of Health & Human Services, 2020). Despite operating as a constraint on state and local authority, such action is likely to support COVID-19 response efforts by increasing the availability of testing, particularly in underserved communities with limited access to health care services.

In other instances, federal preemption laws that predate COVID-19 and new proposals to preempt certain state and local laws have the potential to threaten effective and equitable response and recovery efforts. Proposals to take federal action to shield businesses from state laws imposing civil liability for harms resulting from COVID-19, for example, would remove incentives for businesses to proactively implement health and safety protections, as well as the ability to hold businesses accountable should they cause harm to customers or employees. In a similar way, federal preemption of state and local laws that limit mandatory arbitration clauses in employment contracts closes courts to workers and tends to favor employers. This may exacerbate health inequities given that many employees working in essential businesses are people of color, people with low incomes, and other individuals from underserved communities.

Recommendations for Action

Federal government:

- The president should appoint judges receptive to legal theories protective against the misuse of state and federal preemption.
- Congress should not preempt state and local public health safety laws by shielding businesses that fail to protect the health of customers and employees.
- Congress should adopt legislation prohibiting states from preempting local governments from building or expanding access to municipal broadband.
- Congress should amend the Federal Arbitration Act (FAA) to allow state and local laws restricting or prohibiting mandatory arbitration between employers/employees and businesses/consumers.

State government:

- State governments should reject new efforts to restrict local authority to adopt health- and equity-promoting laws and permanently remove existing state preemption of more protective local laws related to COVID-19 response, economic security, equitable housing, municipal broadband, and civil rights.
  - Governors and other authorized officers should use their emergency powers to suspend preemptive laws preventing effective and equitable local responses.
  - Where necessary, state legislatures should amend state emergency laws to authorize the suspension of preemptive laws.
- Legislatures should repeal all state preemption laws that penalize localities or local officials that enact, enforce, or attempt to enact or enforce preempted or potentially preempted laws (e.g., laws subjecting localities and local officials to fines, civil liability, removal from office, and loss of funding).
- Those responsible for appointing judges, and voters in states that elect judges, should select judges receptive to legal theories protective against the misuse of state preemption.
- Legislatures, and voters in states that allow voter initiatives, should adopt structural reforms to strengthen home rule in alignment with the National League of Cities *Principles of Home Rule for the 21st Century* (National League of Cities, 2020).

Local government:

- Local governments and residents should support resolutions, lobby state lawmakers, and call for state executive action in support of local authority to enact more protective laws related to COVID-19 response (e.g., mask and physical distancing mandates), economic security (e.g., minimum wage, paid leave, employment protections), equitable housing (e.g., eviction moratoria, rent control, source-of-income antidiscrimination), municipal broadband, and civil rights (e.g., antidiscrimination laws, sanctuary cities).
- Local governments and residents should advocate for state legislation or ballot measures expanding home rule authority in alignment with the National League of Cities *Principles of Home Rule for the 21st Century* (National League of Cities, 2020).

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Beyond the Pandemic: Historical Infrastructure, Funding, and Data Access Challenges in Indian Country

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SUMMARY. The COVID-19 pandemic has disproportionately impacted Tribal communities, in part, due to the historical inequities that Tribes have faced for centuries. As sovereign nations, Tribes have the authority to self-govern their people and land. However, the federal government has a special trust responsibility and treaty obligations to Tribes that it often has failed to fulfill. As a result, many Tribal communities live in inferior living conditions as compared to their non-Native counterparts. This Chapter builds on the prior report to explore the historical inequities Tribes experience and how they have been compounded by the pandemic. More specifically, it identifies persistent challenges with infrastructure in Indian Country. It also provides a legislative update on laws directly related to the pandemic as well as laws that have the potential to address some of the issues underlying the pandemic. It concludes by identifying additional recommendations to right these historic wrongs and build on the resiliency shown by Tribes during the pandemic.

Introduction

In *Volume I* of this report, we identified the foundational principles governing Tribal public health systems; discussed their relationship to state and federal governments; and made initial recommendations on improving Tribal health outcomes. This second Chapter focuses on the inequities exacerbated by COVID-19 in Tribal communities and provides additional recommendations to remedy the disparities experienced as a result. While this Chapter highlights some areas of historical inequalities, it is not exhaustive of all issues, such as barriers to economic development and employment. Additionally, at the time of this publication, the country is in the first stages of vaccine distribution. While this implicates Tribal sovereignty and raises issues related to medical research ethics, these issues are outside the scope of this Chapter and were not discussed.

Historical Inequities in Indian Country

In Volume I, we identified the persistent failures of the federal government to honor its treaty obligations to Tribes. One of the main failures has been the chronic underfunding of Indian Health Service (IHS) — the federal agency responsible for providing health care to Native Americans and federal Indian health programming. However, other factors, such as the built environment, play an equally important role in health. The lack of infrastructure, pervasive across Indian Country, has made it difficult to follow the Centers for Disease Control and Prevention (CDC) recommendations regarding COVID-19 prevention, and contributed to the elevated incidence rate of COVID-19 among Native Americans.

To minimize the spread of COVID-19, the CDC recommends avoiding close contact with others. Many Tribes experience chronic housing shortages, making it difficult to take this precaution. Native Americans are one of the fastest growing populations. However, the existing housing in many Tribal communities is insufficient to meet the growing needs. "Forty percent of on-reservation housing is considered substandard (compared to six percent outside of Indian Country)" (National Congress of Indians, 2020). Additionally, the limited housing available is often a significant monthly expense. Almost one-fourth of Native households pay 30% or more of their household income for housing. Lack of safe, affordable housing on reservations further contributes to overcrowding and other conditions incompatible with social distancing and, when necessary, quarantine. These homes often lack basic amenities that the rest of America views as a staple of life in the 21st century, e.g., water, phone service, and broadband.

Access to clean water is also a contributing factor to the high spread of COVID-19 in Tribal communities. To minimize the risk of contracting COVID-19, the CDC recommends washing hands frequently and cleaning surfaces with soap and water. Lack of indoor plumbing has been strongly associated with the incidence of COVID-19 cases on reservations (Rodriguez-Lonebear et al., 2020).

Water is an essential requirement for good health; it is essential to basic personal hygiene, domestic cooking and cleaning, and other aspects of household and community life. And yet, race is the strongest predictor of water and sanitation issues. Native Americans are 19 times more likely than white households to lack indoor plumbing with running water (Roller et al., 2019).

Water access is particularly challenging for the Navajo Nation, which has the largest and most populous reservation in the country. Navajo residents are 67 times more likely than other population groups to live without access to running water. These residents must haul water, often from long distances, to meet their basic household needs. Aside from the time involved, hauling water is also more costly. Navajo families that haul water spend an estimated $43,000 per acre-foot of water compared to the average American family with piped water delivery that spends $600 per acre-foot of water. "This water is among the most expensive in the U.S. for a sector of the population that is among the poorest" (Bureau of Reclamation, 2018). In order to conserve available options, Navajo residents are forced to make decisions that may negatively impact their health. For example, soda and other sugary beverages are more readily available than potable water. Therefore, many residents may choose to drink soda to save money and conserve their limited water, even though drinking these beverages can contribute to obesity and diabetes. The Coronavirus Aid, Relief, and Economic Security (CARES) Act allocated $5 million to IHS to support installation of transitional water points, payment of water fees, purchase of water storage containers, and water disinfection tablets (The Navajo Nation, 2020). While this initial funding will help provide water access to some homes, it does not address the extensive lack of infrastructure on the Navajo Nation. More than $700 million is needed to fund existing, high priority projects identified by the Navajo Nation. And to truly address the widespread lack of water access on the Nation, $3 billion to $4 billion would be required.

Finally, in the technological age that we live in, broadband has been recognized as a human and civil right as well. But, a digital divide exists in America between rural and urban areas that is particularly felt in Indian Country. In a 2018 report, the Government Accountability Office (GAO) found that only 65% of residents on Tribal lands had access to fixed broadband services, and only 69% of households on Tribal lands had telephone services. Limited broadband and phone services have been significant challenges to working remotely during the pandemic. It has also impacted education. During the pandemic, Bureau of Indian Education (BIE) estimates that up to 95% of students at BIE facilities lack residential internet services. For additional information on broadband services, see Chapter 32.

Promising Legislation to Build Infrastructure

When the federal government removed Tribes to reservations, it promised that those lands would be a permanent homeland for the Tribes. As part of its trust responsibility, the federal government has a duty "to protect tribal treaty rights, lands, assets, and resources" (Bureau of Indian Affairs). The persistence of the inequities discussed above reflect the federal government's failure to uphold its trust responsibility to protect tribal lands and

Table 12.1. Actions by 116th Congress to Support Tribal Infrastructure

DRINKING WATER PROGRAMS AND RELATED INFRASTRUCTURE PROJECTS	
S. 4168 (A bill to require the Secretary of HHS to award additional funding through the Sanitation Facilities Construction Program of the IHS, and for other purposes)	Recognizes the association between lack of infrastructure and sanitation and the high incidence of COVID-19 in Tribal communities; and calls on the U.S. Secretary of the Department of Health and Human Services (HHS) to award funding for water infrastructure projects, including $1.45 billion for IHS.
S. 4188 (Water for Tomorrow Act)	Provides $100 million to U.S. Department of the Interior in grant funding to help disadvantaged communities meet drinking water standards and address declining drinking water quality and access.
H.R. 2 (Moving Forward Act)	Provides $2.67 billion to HHS for each fiscal year 2020 through 2024 to effectuate the design, construction, and improvement of water sanitation facilities that are funded at least in part by IHS.
H.R. 8271 (Environmental Justice Legacy Pollution Cleanup Act of 2020)	Provides $3 billion to IHS to provide safe drinking water and adequate sewer systems in Native American homes.
S. 3044 (Western Tribal Water Infrastructure Act)	Amends the America's Water Infrastructure Act of 2018, would make funding for drinking water infrastructure projects on reservations mandatory and increase appropriations to the Indian Reservation Drinking Water Program from $20 million to $30 million.
BROADBAND	
H.R. 1144 (Broadband for All Resolution of 2020)	Recognizes access to affordable and reliable broadband service is a civil and human right and calls on the president to 1) preserve and build the technological leadership of the federal government and funding opportunities to provide affordable broadband access; 2) ensure tribal sovereignty over access to electromagnetic spectrum on Tribal lands; and 3) address the civil and human rights threats posed by lack of affordable access to broadband.

ensure Indian Country is a permanent, habitable homeland. Over the course of 2020, the 116th Congress introduced legislation and resolutions that have the potential to address some of these underlying inequities and uphold the federal trust responsibility. Some of those actions are identified in Table 12.1.

Congressional action that addresses infrastructure in Indian Country is an important step in remedying the historical inequities plaguing Tribes. In addition, there have also been some legislative efforts to more broadly strengthen Tribal sovereignty as well. The Progress for American Indians Act (Pub Law No. 116-180) was enacted on October 21, 2020. The law amends the Indian Self-Determination and Education Assistance Act to further support self-governance by Tribes. The Act allows Tribes to receive grants to plan for participation in self-governance and to negotiate the terms of participation; it also revises the Department of Interior's process for approving self-governance compacts and funding agreements with Tribes. Congress also passed a resolution declaring racism a public health crisis (S. Res. 655/H. Res. 1069). The resolution recognizes,

> "the United States ratified over 350 treaties with sovereign indigenous communities, has broken the promises made in such treaties, and has historically failed to carry out its trust responsibilities to Native Americans … as made evident by the chronic and pervasive underfunding of the Indian Health Service and Tribal, Urban Indian, and Native Hawaiian health care, the vast health and socioeconomic disparities faced by Native American people, and the inaccessibility of many Federal public health and social programs in Native American communities" (S. Res. 655/H. Res. 1069).

Update on Congressional Funding to Tribes

As outlined in Volume I, Congress's major COVID-19 legislative package, the CARES Act, authorized $8 billion in financial assistance to Tribes and Tribal business entities, federal agency Tribal set-asides, and additional funding for certain existing Tribal programs. Tribes have used CARES Act funding for health care facility construction, per capita distributions to citizens, and community gardens, among many other response efforts. However, reports suggest some inconsistencies of funding across Tribes with similar populations (Harsha, 2020).

Federal administration of CARES Act funding through the U.S. Department of Treasury has been inconsistent, with frequent policy changes directing how the funding could be used. In a September 2020 statement, President Shelley Buck of the Prairie Island Indian Community stated, "Until we actually get guidelines from the Treasury that are set in stone, that don't keep changing, we're almost afraid to use the money because we don't want to have to pay it back." Initially, the funding could only be used for expenses incurred through December 30, 2020, leaving a short window to spend the money given the inconsistent administration of the funding (U.S. Department of Treasury, 2021). The COVID-19 stimulus package, discussed below, extended this deadline to December 31, 2021.

The CARES Act also authorized funding to Alaska Native Corporations (non-governmental entities), which has resulted in litigation. Several Tribes have sued the Department of Treasury arguing that Alaska Native Corporations do not meet the definition of Tribal governments under the law and the money should only be distributed to Tribal governments. The D.C. Circuit court ruled that these corporations are not eligible for CARES Act funding. The U.S. Supreme Court recently granted certiorari to review petitions from the Treasury Secretary and several Alaska Native Corporations challenging the D.C. Circuit decision. The Department of Treasury has not distributed money earmarked for Alaska Native Corporations pending this litigation.

The latest COVID-19 stimulus package, passed by Congress on December 21, 2020, included a variety of provisions related to American Indian and Alaska Native health. As reported by the National Indian Health Board, Congress has authorized funding to IHS, Tribal health facilities, and urban Indian health facilities for vaccine distribution, testing, and mental health services. It also includes funding for Tribal broadband, housing, and nutrition programs. In the package, Congress has also reauthorized funding for the Special Diabetes Program for Indians for three more years, through 2024. Unfortunately, this reauthorization remained at existing 2004 funding levels without the additional $50 million minimum requested by Tribes.

Public Health Data Access

Volume I outlined the importance of public health surveillance to COVID-19 response efforts and persistent data quality issues regarding American Indians and Alaska Natives due to racial misclassifications and omission from data collection, among other reasons (Tribal Epidemiology Centers, 2013). Reports have indicated that both Tribes and Tribal Epidemiology Centers (TECs) have been denied timely access to COVID-19 data implicating their communities. Several states have denied Tribal access to data citing that Tribes are not public health authorities (Hoss, 2021). Such statements are incorrect. Tribes are not only governmental public health authorities, but are also public health authorities under the Health Insurance Portability and Accountability Act (HIPAA), entitling Tribes to access otherwise protected health information. Similarly, the CDC failed to respond to numerous requests by TECs for COVID-19 data for months. Under HIPAA, TECs are authorized to have access to protected health information and federal law also requires HHS to facilitate TEC data access.

The Tribal Health Data Improvement Act of 2020 was introduced by Rep. Greg Gianforte, a Republican from Montana, on August 7, 2020. It reaffirms Tribal and TEC access to public health data and requires HHS to make public health data available within 30 days. The act also would require the CDC to develop guidelines to facilitate and encourage state and local health departments to enter into data sharing agreements with Tribes and TECs and to improve the quality of American Indian and Alaska Native-related data collection. The Act passed the House and was sent to the Senate and referred to the Committee on Indian Affairs on September 30, 2020. As of February 15, 2021, no further action on the legislation has been taken. While there have been some discussions regarding Tribal versus TEC access to data, it is critical that Congress take legislative action to ensure Tribal exercise of self-governance in the form of data access.

Recommendations for Action

In addition to the recommendations in Volume I of this chapter, we offer the following recommendations:

Federal government:

- The federal government must recognize that treaty and trust responsibilities include the provision of basic amenities necessary to life, including clean water access, safe and adequate housing, and broadband.
- Congress should pass legislation to reaffirm Tribal authority to public health data and to facilitate access from federal and state governments.
- Congress should pass legislation, such as those identified in this Chapter, for infrastructure projects in Indian Country; and direct federal agencies to work together to maximize and pool funding for such projects.
- The federal government must ensure Tribal sovereignty over access to electromagnetic spectrum on Tribal lands.
- Congress should pass legislation to reaffirm Tribal and Tribal Epidemiology Center (TEC) data access.
- The federal government should create incentives for state and local governments to share data with Tribes and TECs and enter into data sharing agreements.

State and Local governments:

- State governments must recognize the basic human right to water that is separate from water settlements or other negotiations between states and Tribes.
- State and local governments must improve data quality regarding American Indian and Alaska Native health records and provide data access to Tribes.

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PART 3

Financing and Delivering Health Care

Private Insurance Limits and Responses

Elizabeth Weeks, JD, University of Georgia School of Law

SUMMARY. 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. Shelter-in-place orders, social distancing, and other public health strategies employed to address the pandemic spawned a global recession, causing rapid and high unemployment rates in many countries. The U.S. unemployment rate peaked in April 2020 at 14.7%, higher than in any previous period since World War II. The United States has long hewed an anachronistic policy of relying heavily on private employers to provide health insurance to a substantial portion of the population. Those who are not eligible for employer-sponsored insurance (ESI) must fend for themselves in the non-group market, unless they qualify for government-sponsored insurance or safety net programs. Companion Chapters in this volume describe the COVID-related challenges for Medicaid and the uninsured, while this Chapter focuses on the private insurance market. The Patient Protection and Affordable Care Act of 2010 (ACA) dramatically overhauled health insurance in the United States. But those reforms have been under continuous threat of dilution or wholesale repeal, including a case currently pending before the U.S. Supreme Court that could strike down the entire act. Notwithstanding the change in administration, any evaluation of the benefits or demerits of the private insurance market must be read against the possibility that existing consumer protections could be eliminated with the stroke of a pen.

Introduction

The ACA enacted a comprehensive strategy to extend health insurance to more than 20 million previously uninsured individuals and families in the United States. Even at the time of enactment, many viewed the ACA as a fragile compromise and second-best solution to U.S. health care fragmentation. The COVID-19 pandemic casts in stark relief the limits of the ACA's initial design as well as its steady erosion through legal challenges, implementation hurdles, executive orders, and partisan politics. The United States' overreliance on ESI, limited public entitlements, and the "Wild West" of an individual insurance market fail to serve the population's health care needs under normal circumstances, not to mention during a global pandemic and economic recession.

The COVID-19 pandemic exposed key coverage gaps as well as long-standing inequities in health insurance and access to care. Those realities of the existing private insurance market presented numerous difficulties and considerable uncertainty for customers, including coverage for COVID testing and treatment, enrollment restrictions, and unexpected billing for out-of-pocket and out-of-network costs. The working population is at risk of losing insurance coverage if they become unemployed. Those who are lucky enough to retain their jobs are also at risk, however: the underinsured population has steadily grown in recent years, and those who need medical treatment but are unable to pay expensive out-of-pocket costs may avoid treatment or incur crippling medical debt. The patchwork system of private health insurance is battered on two sides: first, by a global pandemic that has required costly treatment for millions who cannot afford it, and second, by an economic crisis that this fragile system is unable to withstand.

ACA Private Insurance Reforms

With respect to ESI, the ACA requires large employers (at least 50 full-time-equivalent employees) to offer affordable, minimum-value coverage to employees. Coverage is "affordable" if self-only coverage costs no more than roughly 10% of the employee's household income. Coverage is "minimum-value" if the plan pays, on average, at least 60% of the cost of covered services.

With respect to individual and small-group plans, the ACA dramatically overhauled both markets. Two of the key reforms include eliminating pre-existing condition exclusions and disallowing premium-rate variation based on individual risk factors, with limited exceptions. Premium-rate variation means insurers may charge different premium rates based on where the plan is sold, plan type (individual or family), age, and tobacco use. Those provisions are significant for COVID-19 coverage because they would seem to allow individuals and families to obtain coverage, without price gouging, even after being diagnosed or for the purpose of being tested.

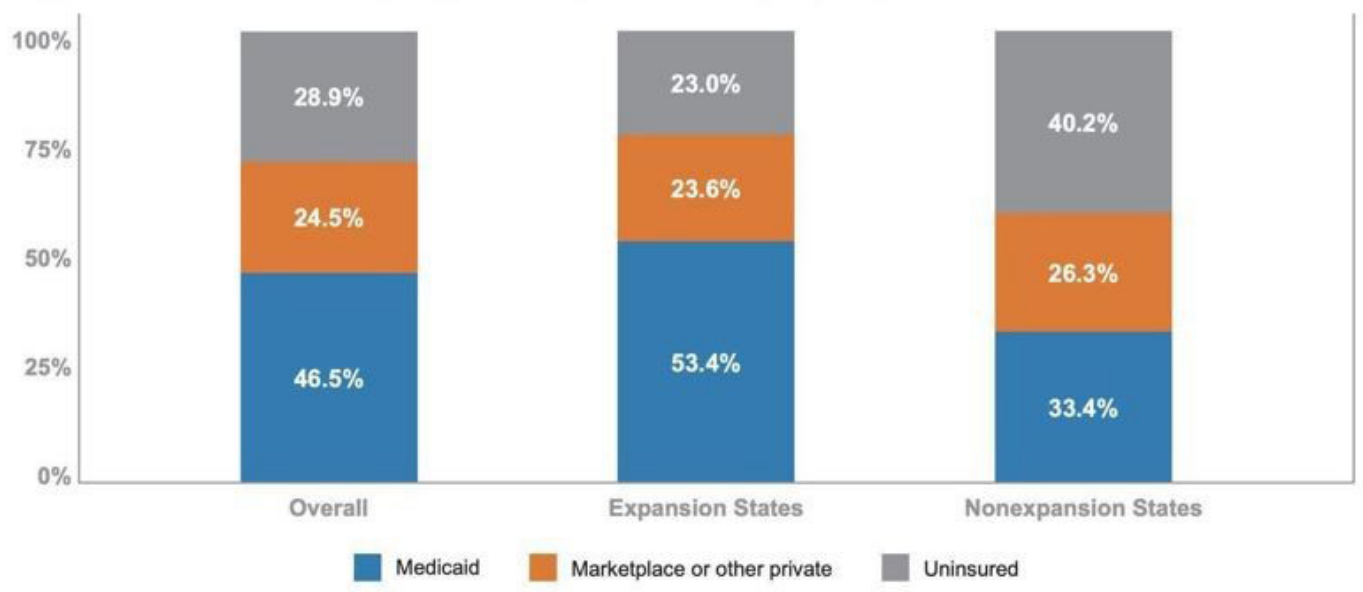


Figure 13.1: Estimated Coverage Types of People Losing Employer-Sponsored Health Insurance. Source: Urban Institute/Robert Wood Johnson Foundation, 2020.

The health insurance marketplaces are another critical component of the ACA's statutory design to create a more accessible market for private health insurance. Marketplaces, operated by states or the federal government, operate in each state and facilitate comparison among policies, enrollment, and access to federal subsidies. Plan enrollment is limited to certain times of the year, absent an applicable exception, as described more fully below. Consumers purchasing marketplace plans are eligible, depending on income level, for either premium-assistance tax credits, which lower monthly premiums, or cost-sharing reduction (CSR) payments, which lower out-of-pocket costs for deductibles, co-insurance, and co-payments.

All non-group plans, both marketplace and non-marketplace, must comply with the ACA's broad coverage mandate, meaning that plans must offer a package of "essential health benefits" (EHB), defined by reference to state benchmark plans, which typically include acute inpatient care, urgent care, emergency room care, and outpatient care. The EHB requirement does not apply to ESI.

Both marketplace and ESI plans operate under annual open enrollment periods, meaning they are available for enrollment only once a year, for a limited time period. Open enrollment is subject to certain "life event" exceptions, such as becoming unemployed or experiencing a death in the family. Those life events trigger special enrollment periods (SEPs), which typically provide 60 days before or after the event to enroll. These rules limit influx during the plan year, thereby helping insurers better predict costs and set premium rates. They have the effect, however, of at least delaying some consumers from accessing health insurance, even though they cannot be excluded based on preexisting conditions. In the COVID-19 context, that means that individuals without a qualifying life event, seeking insurance outside of the annual open enrollment period, would be out of luck.

Coverage Requirements and Out-of-Pocket Limits

Several ACA requirements apply to both ESI as well as individual and small-group plans. Plans must cover preventive care, such as vaccinations, without requiring co-payments, co-insurance, or deductibles, called "first-dollar" coverage. Also, plans may not impose lifetime or annual caps on EHB and are subject to annual out-of-pocket cost limits on covered EHB, meaning all benefits after the limit is hit must be provided without cost-sharing. For 2020, the out-of-pocket limit was $8,150 for individual coverage and $16,300 for family policies. Although ESI plans are not required to cover EHB specifically, the EHB definition is relevant for applying these caps.

States may impose additional coverage or other requirements on individual and small-group plans. Those additional requirements, however, do not apply to self-insured ESI plans because of sweeping federal preemption provisions in the Employee Retirement Income Security Act of 1974 (ERISA). About 60% of people who receive insurance through employers are in self-insured plans. That means that even if states enact broader COVID-19 coverage provisions or other consumer protections, a considerable number of insured individuals would not benefit from those reforms. An employer "self-insures" when it bears the financial risk of the medical claims rather than purchasing a group health plan for its employees. Many large employers opt for self-insuring, as it is less costly to directly pay for employees' medical bills. By contrast, under an "insured" ESI plan arrangement, the health insurer is the financial risk-bearer, and the employer pays premiums to the insurer on behalf of the entire group.

Private insurance enrollment has declined drastically since the start of the pandemic. Although the reduction in ESI was offset in part by a corresponding rise in public insurance coverage, the number of uninsured adults still increased by roughly two million.

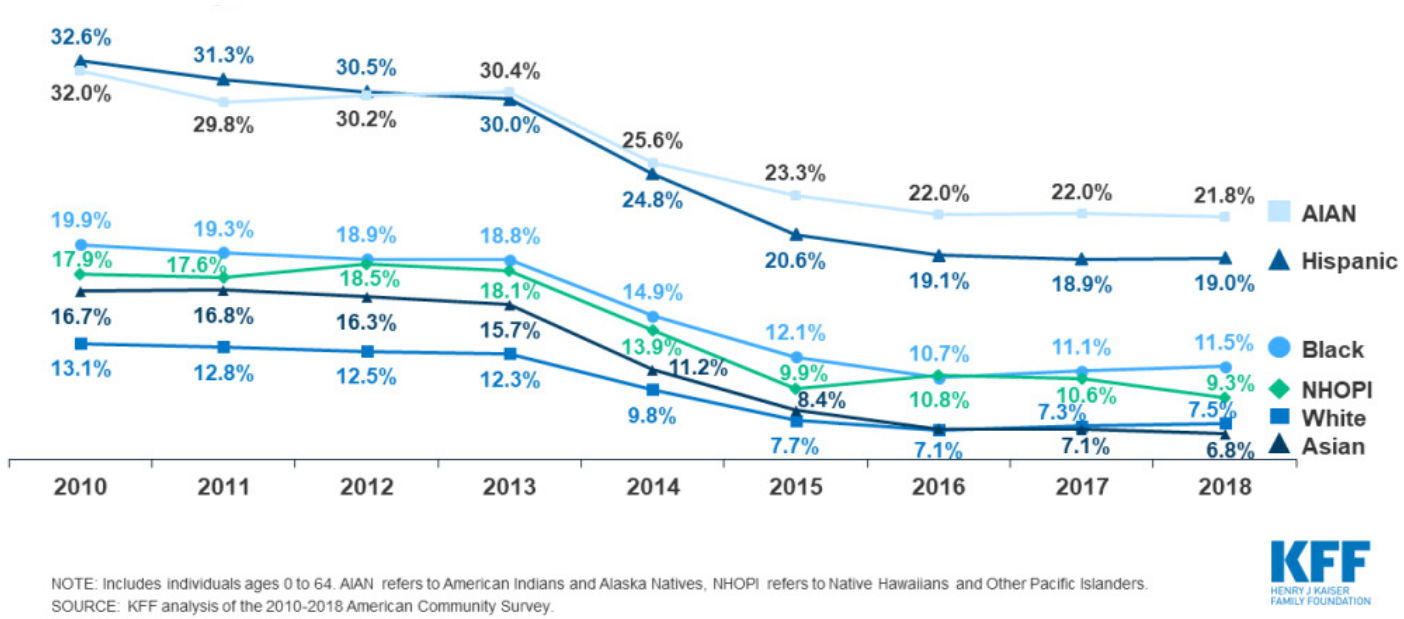


Figure 13.2: Uninsured Rates for the Nonelderly Population by Race and Ethnicity, 2010-2018. Source: Samantha Artiga & Kendal Orgera, Kaiser Family Foundation, 2020.

Those groups that saw the largest ESI losses, Hispanic adults, non-Hispanic Asian adults, men, adults without a college degree, and adults aged 18-39, also saw the largest increases in un-insurance.

The recession caused by the COVID-19 pandemic is the first to not only test the limits but also the positive impact of the ACA. Enrollment in Medicaid for low-income Americans and a tax credit program for low- and middle-income Americans who are buying their own health insurance through the ACA marketplace has increased since the beginning of the pandemic. Declines in ESI increased in states that did not expand Medicaid under the ACA. However, the rate of un-insurance during this recession is notably lower than those in past economic downturns.

Inadequate Coverage and the Rise of the Underinsured

Those who benefit from private insurance options like ESI or a marketplace plan are not necessarily protected from unaffordable health care costs. Many who have insurance are underinsured, which means they have disproportionately high out-of-pocket costs relative to their household income. Uninsured individuals are also much more likely to be unable to pay their medical bills, and thus are more likely to incur medical debt. Many who incur this debt find that they are unable to pay their bills while simultaneously paying for necessities such as food, heat, and housing.

Among those insured in private health plans, those 15 million who were enrolled in plans they purchased on the individual market were underinsured at the highest rates. In addition, 25% of the 122 million adults with ESI were underinsured. A study by the Commonwealth Fund found that growth in the underinsured population since 2010 has been mostly driven by increasingly inadequate coverage in employer health plans. Businesses have responded to rising health insurance prices by saddling employees with more out-of-pocket costs. Deductibles, for example, had more than tripled. This rise in costs could conceivably result in greater marketplace participation, although there are many who do not qualify for Medicaid but are still unable to afford marketplace coverage.

The Black population and other nonwhite minority groups are significantly more likely to be underinsured than the white population. The country's reliance on tax-subsidized ESI and history of race-based employment discrimination means that nonwhite groups are particularly likely to experience underinsurance. People of color are also more likely to be infected with COVID-19 than white people. If they are forced to choose between feeding their families and paying for a doctor's visit, it is not unlikely that they will avoid treatment. During a global pandemic, those who avoid treatment due to an inaccessible health care system will create a greater risk for themselves, their communities, and the rest of the country.

In order to reduce the underinsured population and encourage access to COVID-19 testing, treatment, and vaccines, the federal government must collaborate with states to decrease the price of premiums and other out-of-pocket costs by amending federal preemption and increasing regulation of ESI. Particularly during a public health crisis, relying on a piecemeal private insurance system to effectively and affordably cover millions of people without regulations to ensure fairness and equity will only exacerbate the spread of COVID-19 among un- and underinsured populations.

President Biden's health care policy platform expands upon the existing marketplace infrastructure in order to address underinsurance. The platform includes plans to eliminate the 400% income cap on tax credit eligibility and to lower the limit on the cost of coverage from 9.86% of a household's income to 8.5%.

Additionally, the president intends to increase the size of the tax credits themselves by amending the calculations to give more families the ability to afford coverage with lower deductibles and fewer out-of-pocket costs. For families that may still not be eligible for marketplace coverage, there would be a new premium-free public option that would provide insurance for those that have slipped through the cracks of the existing insurance system.

Insurance Coverage for COVID-19

Against that landscape, the COVID-19 pandemic presents a number of challenges for private insurance customers and plans, including coverage for testing and treatment, consumers' exposure to out-of-pocket or out-of-network costs, and enrollment limitations.

Coverage for Testing

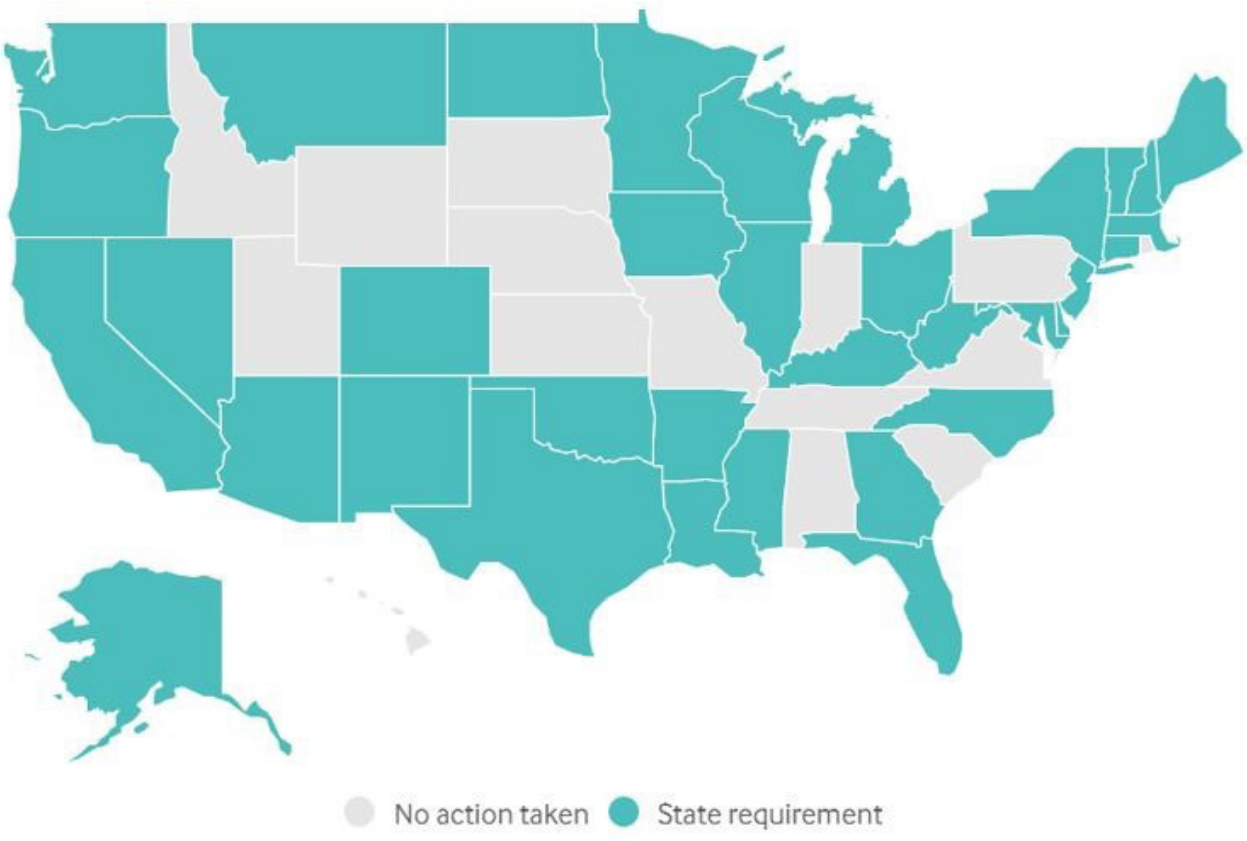
One of the first questions regarding health insurance coverage for the COVID-19 pandemic concerns testing for the virus. The ACA's "first-dollar" preventive care coverage requirement does not clearly encompass diagnostic testing, yet testing is essential for limiting disease spread by identifying infected individuals who should isolate themselves from healthy individuals. Private health plan cost-sharing requirements might deter individuals from getting tested, thereby undermining those public health strategies. In response, Congress has enacted legislation that would require insurance providers to cover testing. It has also appropriated money to go directly to states to cover the cost of testing.

Congress acted quickly after the United States' COVID-19 outbreak in spring 2020 to enact two bills containing provisions related to health insurance coverage. The Families First Coronavirus Response Act (FFCRA) and the Coronavirus Aid, Relief, and Economic Security (CARES) Act require all ACA-compliant and other comprehensive group and non-group health insurance plans to cover testing for detection or diagnoses of COVID-19 and the administration of that testing. FFCRA covers testing for both the active coronavirus infection as well as serological tests for the COVID-19 antibody. The coverage requirement only applies during a federal public health emergency declaration, which HHS Secretary Alex M. Azar renewed on January 7, 2021. The HHS Secretary may extend this public health emergency declaration for subsequent 90-day periods, for as long as the emergency persists (Centers for Medicare & Medicaid Services, 2020).

Initially, coverage was limited under FFCRA to FDA-approved testing, but the CARES Act extends to (1) tests provided by clinical labs on an emergency basis (including public health labs); (2) state-developed labs; and (3) tests for which the manufacturer says it will seek approval. Coverage also extends to any services or items provided during a medical visit that result in COVID-19 testing or screening.

The laws also specify that COVID-19-related diagnostic testing must be covered like other preventive care under the ACA, that is, without regard to deductibles, co-payments, co-insurance,

Figure 13.3: States requiring additional insurer action. Source: Madeline O'Brien & Sabrina Corlette, The Commonwealth Fund, 2021.



preapproval, or precertification (Keith, 2020a). Under the CARES Act, plans are required to cover COVID-19 vaccines and other preventive measures on a first-dollar basis. This requirement extends to all types of group health plans, including insured and self-insured ESI plans.

The CARES Act addresses provider reimbursement for COVID-19 diagnostic testing, requiring all comprehensive private health insurance plans to reimburse test providers based on the rate negotiated between the plan and the provider. If there is no negotiated rate between the plan and provider (i.e., the provider is out-of-network), then the plan must fully reimburse the provider based on the provider's own, publicly available "cash price" (Keith, 2020a). The Consolidated Appropriations Act (CA Act), signed into law by President Trump on December 27, 2020, provides few additional details with regard to how states must administer and charge for COVID-19 tests, but it does appropriate an additional $22 billion to states for testing, tracing, and other COVID-19 mitigation programs. This includes $2.5 billion specifically for improving testing and tracing for underserved populations.

Coverage for Treatment

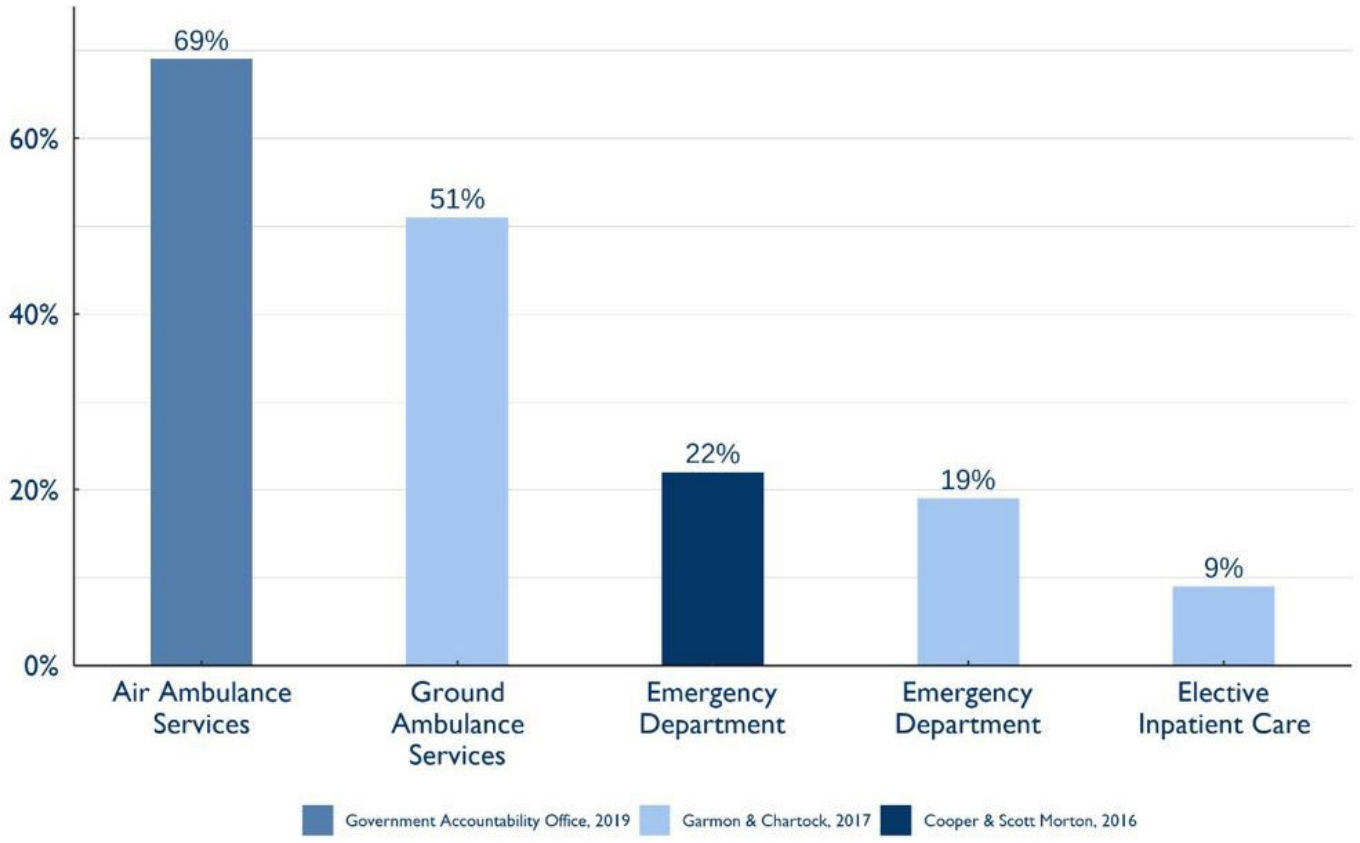
Once an individual is infected with COVID-19 and experiencing acute symptoms, the next concern is coverage for treatment. ACA-compliant plans both on and off the marketplaces typically include such care under EHB. Likewise, comprehensive ESI plans typically cover treatment services.

Consumers' responsibility for treatment costs varies depending on their plans' cost-sharing configurations, coverage terms, and provider networks. The ACA's annual out-of-pocket limit provides some financial protection, but consumers may still face some unexpected out-of-pocket costs. While predictable out-of-pocket costs include deductibles and co-payments, unexpected costs could arise from "surprise" medical bills, typically for out-of-network care (Keith, 2020b). For example, if a hospital-employed anesthesiologist or an on-call emergency room doctor treats a patient even though that provider is not covered by the patient's plan, the provider may later bill the patient directly for the services at out-of-network rates.

The federal government has required private insurers, ESI plans included, to waive cost-sharing for COVID-19 related treatment and testing establishing a baseline level of care throughout the country. States have taken a number of actions expanding the minimum federal requirements of private insurers ranging from requiring off-drug formulary coverage to premium payment relief. The additional requirements imposed upon insurers vary from state to state. For example, some states prohibit insurers from terminating insurance contracts due to nonpayment while others may merely recommend insurers refrain from coverage cancellations (O'Brien, 2021).

The CA Act includes measures to increase transparency and prevent surprise medical billing; beginning on January 1, 2022, patients will be protected from surprise medical bills that may arise

Figure 13.4: Percentage of Visits Leading to Surprise Out-of-Network Bills. Source: Christen Linke Young et al, USC-Brookings-Schaeffer on Health Policy, 2019.



from emergency care they receive from providers outside their networks. A patient may still be billed for out-of-network, non-emergency care, but the patient must provide informed consent, in writing, prior to receiving this care.

Although the surprise billing provision of the CA Act will not be implemented for another year, federal guidance implementing the Provider Relief Fund portion of the law suggests intent to prohibit surprise billing. One of the terms and conditions attached by the HHS to those relief funds stipulates that for all possible or actual cases of COVID-19, the provider (hospital, clinic, or physician practice) cannot charge more for out-of-pocket care than if the provider were in-network or had contracted with the patient's insurance company (Keith, 2020b).

In addition to the above, rather obscure federal guidance, a handful of state insurance regulators have required or encouraged insurers to waive cost-sharing for COVID-19 testing and treatment (Norris, 2020). In terms of state responses, New Mexico, for example, requires health plans to waive cost-sharing for medical services related to COVID-19, pneumonia, and influenza. Massachusetts requires health plans to provide COVID-19 treatment with no cost-sharing, although the mandate is limited to care in a doctor's office, urgent care clinic, or emergency room, and not the more expensive inpatient care. Vermont requires state-regulated health plans to waive cost-sharing for COVID-19 treatment. Minnesota initially issued guidance suggesting that insurers fully cover the cost of testing and limit or eliminate the cost of treatment, then also called for further state legislative response. In all cases, state cost-sharing waivers do not apply to self-insured ESI plans due to ERISA preemption, as explained above.

In states where cost-sharing waivers are not required, a few private insurers have voluntarily issued waivers with varying policies. For example, some of these voluntary waivers apply to both in-network and out-of-network treatment, while others waive cost-sharing for any in-network treatment but only out-of-network emergencies. Most commonly, cost-sharing is waived only for in-network treatment, and in some cases, the waivers have date cut-offs or do not extend to self-insured ESI plans (Konrad, 2020).

Coverage for Vaccination

The CA Act appropriates approximately $30 billion for the federal government to assist with the purchase and administration of the COVID-19 vaccine, as well as other COVID-19-related therapeutics. This includes $8.75 billion to the CDC to plan, prepare for, administer, monitor, and track coronavirus vaccines, and ensure broad distribution and access. Of this, $4.5 billion must be allocated to states, localities, and territories, and an additional $300 million must be allocated to high risk and underserved populations, including racial and ethnic minorities and those living in rural communities.

Open Enrollment Periods

For more information on open enrollment periods, please see the analysis in Chapter 12 in *Assessing Legal Responses to COVID-19: Volume I*.

Recommendations for Action

Federal government

- HHS should open a special enrollment period for all federally-facilitated marketplaces as well as self-insured employer-sponsored insurance plans, irrespective of qualifying life events
- Congress should pass legislation waiving cost-sharing obligations and prohibiting balance-billing for out-of-network charges to self-insured plans.
- HHS should clarify that federal coverage mandates and fee waivers are retroactive to the beginning of 2020 and will continue for the duration of the public health emergency.
- Congress should extend fee waivers for COVID-19 screening and provide that screening may be conducted by an out-of-network provider as long as the member makes a good faith effort to see an in-network provider.
- Congress should authorize COBRA subsidies to help workers and their families maintain continuous, comprehensive coverage.
- Congress should establish a federal vaccination fund, which would allow the federal government, rather than insurance companies or Medicaid programs, to negotiate prices with vaccine manufacturers in order to equitably distribute free virus and serological testing to all Americans as well as reimburse providers for administering these tests based on Medicare rates.
- President Biden should execute an executive order limiting renewals of short-term limited duration plans, thereby, reestablishing their role as stop-gap insurance rather than plans that would divert participants away from ACA-compliant plans.

State governments

- Should open a special enrollment periods and extend their end-dates for state-operated marketplaces in all states.
- States should enact individual health insurance mandates to stabilize risk pools and provide access to timely and appropriate preventive care and other treatment, rather than allowing individual to delay and seek care once conditions become acute, as originally intended under the ACA.
- In the event of wholesale repeal of the ACA states should enact comprehensive reforms, including prohibitions on health-status underwriting and ratemaking.
- States should enact legislation providing for a "public option," publicly funded health insurance, for those who do not qualify for Medicare, Medicaid, other government health care programs, or ESI, that would be included along with private plans offered on the ACA's state-based marketplaces.

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The author would like to thank Somer Brown for her research assistance.

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Lessons Learned: Strengthening Medicaid to Address Health and Economic Emergencies

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SUMMARY. COVID-19 has disproportionately harmed low-income people, especially Black and Latino populations, seniors, and people with disabilities. Medicaid plays an essential role in providing coverage and access to care for these populations. As COVID-19 disrupted employment, earnings, and insurance coverage, Medicaid enrollment increased, in part because Congress offered states increased Medicaid funding in return for maintaining eligibility and enrollment for the duration of the public health emergency (PHE). At the same time, many states expanded eligibility and streamlined enrollment to assure that people could secure and keep coverage. Such policies resulted in more than 5.3 million more Americans having Medicaid coverage during 2020. However, increased demand for Medicaid during the pandemic's economic downturn places pressure on state budgets. The secretary of the Department of Health and Human Services (HHS) and Congress should work together to ensure that the Medicaid enhanced federal match and maintenance of effort requirements continue at least through early 2022 to protect coverage for low-income Americans and to help states weather the economic recovery. HHS should rescind all policies that create barriers to enrollment and access to care. State governments should continue to use temporary emergency authorities to expand eligibility and streamline application and enrollment processes and make them permanent when the PHE ends. Congress should either proceed with President Biden's campaign plan for a federal public option to provide low-cost insurance coverage, particularly important for states that have not expanded Medicaid, or enact an increased federal match for a limited period of time to encourage opt-out states to implement Medicaid expansion.

Introduction: Medicaid's Key Challenges as the Pandemic Began

Medicaid provides medical and long-term care for more 75 million of America's poorest and most vulnerable people, covering nearly a quarter of the population. For decades, Medicaid has covered low-income parents, children, pregnant women, people with disabilities, and seniors. The Patient Protection and Affordable Care Act (ACA) extended eligibility to nonelderly adults including those with no children earning up to 138% of the federal poverty level, narrowing persistent insurance coverage gaps, particularly for people of color and low-wage workers long excluded from employer-sponsored health insurance.

Medicaid is a joint federal-state program that provides open-ended federal matching funds limited only by individual states' contributions. Federal law details mandatory requirements with which state Medicaid programs must comply, but states retain considerable flexibility to cover optional categories of eligibility and services, and to design delivery systems through state plan amendments. States also can seek waivers from the secretary of HHS to use federal Medicaid funds in ways not authorized by federal statute. Many waivers fall under Section 1115 of the Social Security Act, which gives the secretary authority to waive certain provisions of the Medicaid Act to allow demonstration projects that further the objectives of the Medicaid program. Others are authorized by Section 1915(c), which allows home and community-based long-term services and supports. Section 1135 grants the secretary authority to waive additional provisions of the Medicaid Act when the president declares a national emergency and the secretary declares a PHE. For more information on Medicaid's core features and its vital role in responding to the COVID-19 health and economic emergency, see Chapter 13 in *Assessing Legal Responses to COVID-19: Volume I*.

As America entered the pandemic, three key challenges confronted Medicaid. First, a small number of states, primarily in the South, continued to eschew Medicaid expansion, leaving millions of low-income people, especially minority populations, vulnerable to the health and economic emergency that arose. Second, HHS changed long-standing Section 1115 waiver policies to encourage states to limit enrollment, most notably through work requirements and block grants, a policy that contradicts the purpose of Medicaid and the Affordable Care Act. Third, HHS created new policies designed to gut core statutory protections and make it more difficult for people to stay enrolled in Medicaid.

States Opting Out of Medicaid Expansion

Fourteen states have not implemented Medicaid expansion under the ACA. Pre-COVID-19, this left more than two million uninsured adults in a coverage gap, as they did not qualify for Medicaid and earned too little to qualify for federal tax benefits that help pay for private insurance purchased on an exchange. Nine out of 10 people in the coverage gap live in the eight Southern states that have not expanded Medicaid. (Garfield et al., 2020).

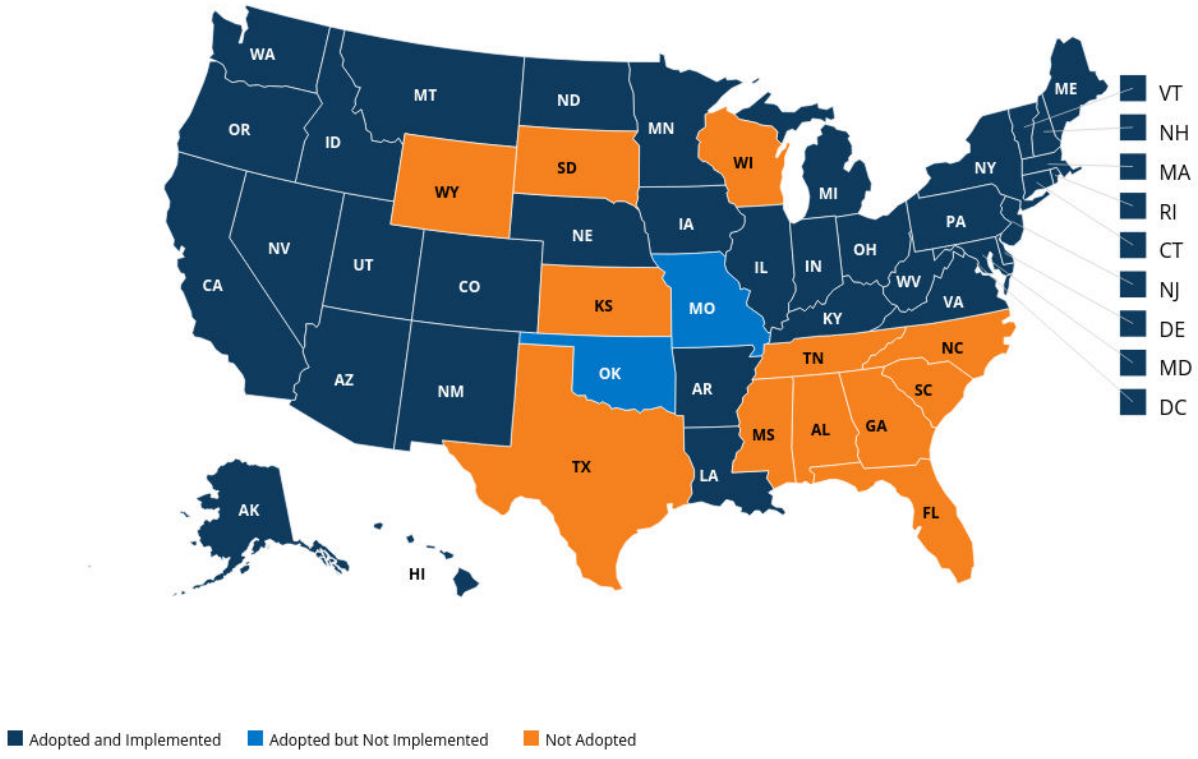
Hundreds of studies show that Medicaid expansion improves coverage and access to care. It is particularly important for minority health: Medicaid expansion helps to address social determinants of health, has reduced historic disparities in coverage and access, and has improved health outcomes for Black and other communities of color. Though states claim they cannot afford it as a reason to opt out, expansion is a financial benefit for states; numerous studies find expansion provides revenue gains and economic growth for states (Guth et al., 2020). Expansion also supports rural hospitals, which are major employers in their communities and are much less likely to close or limit services in Medicaid expansion states (Sheps Center, 2020).

The non-expanding Southern states have stingy Medicaid and other social programs as well as large Black populations, high poverty rates, and the history of slavery and Jim Crow laws that have led to current race-based health disparities. The decision not to expand Medicaid eligibility exacerbates geographic disparities in health coverage, access, and outcomes, and has amplified the economic and health impact of COVID-19 (Artiga et al., 2019). According to an Urban Institute study, about 40% of people losing employer-sponsored coverage during the pandemic in non-expansion states are expected to become uninsured (Garrett and Gangopadhyaya 2020).

New 1115 Waiver Policies Establishing Barriers to Enrollment

The secretary of HHS has authority under Section 1115 to waive specific Medicaid Act provisions, which allows states to conduct time-limited demonstration projects that further Medicaid's objective to provide health care for low-income people. Prior administrations focused on increasing eligibility, expanding benefits, and improving delivery systems. However, in November

Figure 14.1. Status of State Action on the Medicaid Expansion Decision



SOURCE: Kaiser Family Foundation, kff.org

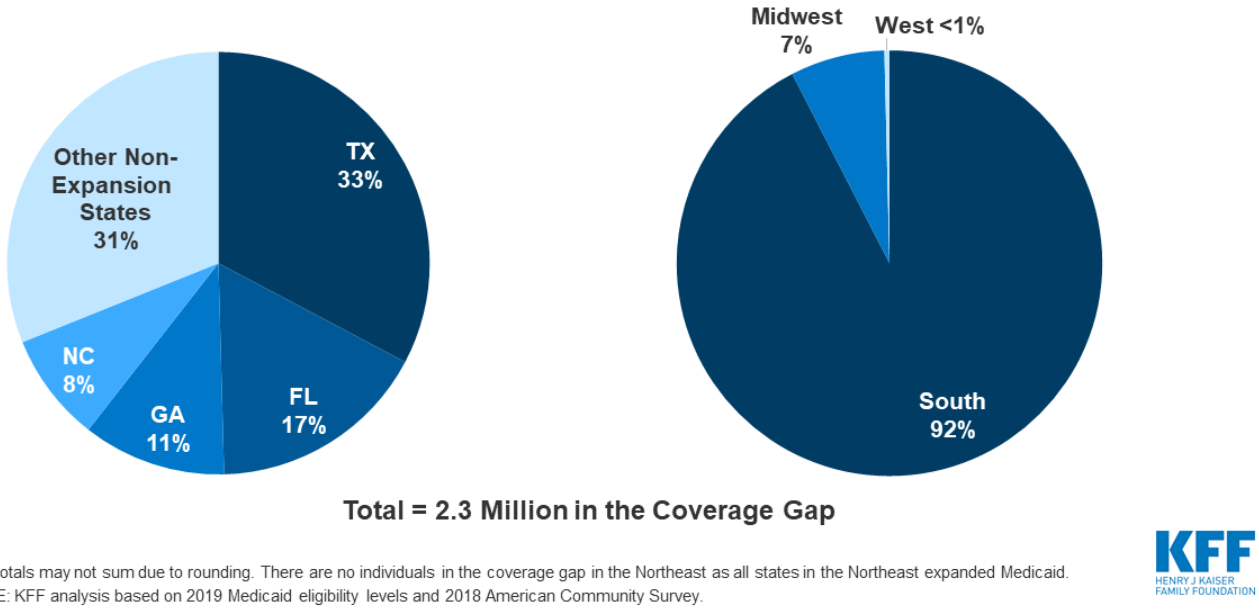


Figure 14.2. Distribution of Adults in the Coverage Gap, by State and Region, 2018. Source: Kaiser Family Foundation.

2017, HHS posted revised criteria for evaluating 1115 waiver applications (CMS, 2017). The revision deleted expanded coverage as an objective, instead targeting novel goals like positive health outcomes, program sustainability, upward mobility, responsible decision-making, alignment with commercial health plans, and "innovative" payment and delivery systems. The revision illustrates how the Trump administration sought to reshape Medicaid through sub-regulatory guidance and waivers that limit eligibility, reduce benefits, and cap federal matching funds.

A January 2018 State Medicaid Director Letter encouraged waiver proposals that impose work reporting requirements as a condition of Medicaid eligibility for both expansion enrollees and traditional populations, like low-income parents (CMS, 2018). This letter reversed the position of previous Republican and Democratic administrations, which refused to approve such waiver requests because they did not further Medicaid's objectives of promoting coverage and access. As of January 2021, eight states had approved work requirement waivers and seven more had requests pending. Another four states (Arkansas, Kentucky, Michigan, New Hampshire) had waiver approvals stayed by federal courts.

So far, federal courts have found that the objective of Medicaid is to provide medical care, and the Secretary of HHS acts in an unlawful arbitrary and capricious fashion when he ignores the decreased coverage work requirements predictably cause. In Arkansas, the only state to implement a work requirement waiver, more than 18,000 people, about 25% of the individuals who were subject to the work requirement, lost coverage in the first five months (*Gresham v. Azar*, 2020). The Supreme Court granted *certiorari* in the cases involving Arkansas and New Hampshire, with oral arguments set for late March 2021. Notably, HHS approved work requirement waivers for very low-income parents and others in Georgia and South Carolina, both non-expansion states.

Additionally, in January 2020, Centers for Medicare and Medicaid Services (CMS) issued a new State Medicaid Director Letter inviting applications for "Healthy Adult Opportunity" (HAO) waivers (CMS, 2020b). This policy gives states "extensive flexibility" to use Medicaid funds to cover ACA expansion adults, and other "optional" nonelderly adults who do not qualify on the basis of disability, without having to comply with federal Medicaid Act standards for eligibility, benefits, delivery, and oversight. In return, states agree to convert federal Medicaid funding to capped funding structured as an annual block grant or a per capita cap. In the final days of the Trump administration, CMS approved an amendment to Tennessee's existing 1115 waiver, a modified block grant structure that was filed before the HAO policy was announced but incorporates many of its features. The waiver approval exceeds the secretary's authority under Section 1115 and is certain to face legal challenges. But, the administration's attempt to cap federal matching funding by offering states discretion to cut eligibility and benefits destabilizes Medicaid's financing structure and threatens its consumer protections at the very moment more people are turning to Medicaid for coverage.

Both of these policies undermine the purpose of Medicaid, to pay for coverage and care for low-income populations. These policies also contradict the purpose of the ACA, to attain near-universal insurance coverage through a combination of public and commercial insurance. These Trump administration policies made enrollment more difficult and sought to roll back the ACA Medicaid expansion.

Additional HHS policies creating barriers to care and continuity of coverage

The Trump administration approved a variety of other 1115 waivers that impose enrollment and coverage restrictions on both expansion and traditional Medicaid populations, in both expansion and non-expansion states, that no other administration has allowed (Kaiser Family Foundation, 2020). These waivers include:

- charging premiums above the amounts allowed by federal law (AR, AZ, IA, IN, MI, MT, GA, IN, WI),
- coverage lock-outs for failure to timely renew coverage, report changes affecting eligibility, and non-payment of premiums for non-expansion populations (IN, MI, MT, WI),
- elimination of Medicaid's standard three-month retroactive coverage for nearly all enrollees, including seniors and people with disabilities (AZ, IA, IN, FL, GA, IA),
- making coverage effective the date of the first premium payment instead of the date of application (IN, GA),
- elimination of payment for non-emergency transportation (IA, IN, UT, GA).

The Trump administration also promulgated a sub-regulatory policy designed to make it more difficult to maintain coverage. A June 20, 2019, "Oversight of State Medicaid Claiming and Program Integrity Expectations" guidance encourages states to conduct more frequent eligibility verifications to reduce the number of ineligible people enrolled in Medicaid. However, research and experience show that increased verification requirements lead to decreases in coverage for eligible people who have difficulty providing documentation and navigating administrative processes (Artiga & Pham, 2019).

Before the pandemic, precipitous Medicaid enrollment declines in Missouri, Tennessee, Arkansas, Louisiana, and Texas suggested that growing use of periodic eligibility checks and heightened renewal verification requirements contributed to disenrollment among people legally eligible for coverage as well as increased coverage churn (Artiga & Pham, 2019). Implementation of Medicaid expansion in 2014 led to steadily increasing enrollment for both adults and children. Yet, between December 2017 to June 2019, Medicaid enrollment declined by 2.4 million, a drop that cannot be attributed solely to economic conditions because the uninsurance rate increased. For example, between 2017 and 2018, the uninsured rate increased from 7.9% to 8.5%, driven in part by decreased Medicaid and CHIP coverage (Artiga & Pham, 2019).

Adapting Medicaid during the Pandemic

Medicaid is an important crisis response program because it provides states with open-ended federal funding that increases to match state Medicaid spending increases, which inevitably happens during an emergency. Medicaid enrollment is countercyclical. When the economy deteriorates and unemployment rises, enrollment increases just when states, which must have balanced budgets, experience decreased tax revenues due to a downturn. Congress anticipated that the pandemic would place additional demands on Medicaid and moved quickly to provide states with enhanced funding on the condition that states protect eligibility and enrollment during the pandemic. Many states went further, taking advantage of temporary regulatory flexibilities to streamline eligibility and enrollment during the COVID-19 PHE.

Congress: Enhanced FMAP and Maintenance of Effort

Congress's first COVID-19 economic stimulus package, the Families First Coronavirus Response Act (Families First Act), offered states a 6.2 percentage point increase in federal matching funds for non-expansion Medicaid spending for the duration of the PHE. To qualify for the enhanced match, states must maintain eligibility and provide continuous Medicaid enrollment for the duration of the pandemic (maintenance of effort, or "MOE," requirements). States may not limit eligibility, impose more restrictive eligibility procedures, charge higher premiums, or disenroll currently or newly enrolled beneficiaries unless they die, move, or request to be disenrolled. All states have accepted the enhanced federal match and are subject to MOE requirements.

The Families First Act effectively paused Section 1115 waiver approvals imposing work requirements, premiums, and other barriers to enrollment and continuous coverage. It also suspended frequent and disruptive redeterminations of eligibility. For the duration of the PHE, states may not terminate enrollees from Medicaid.

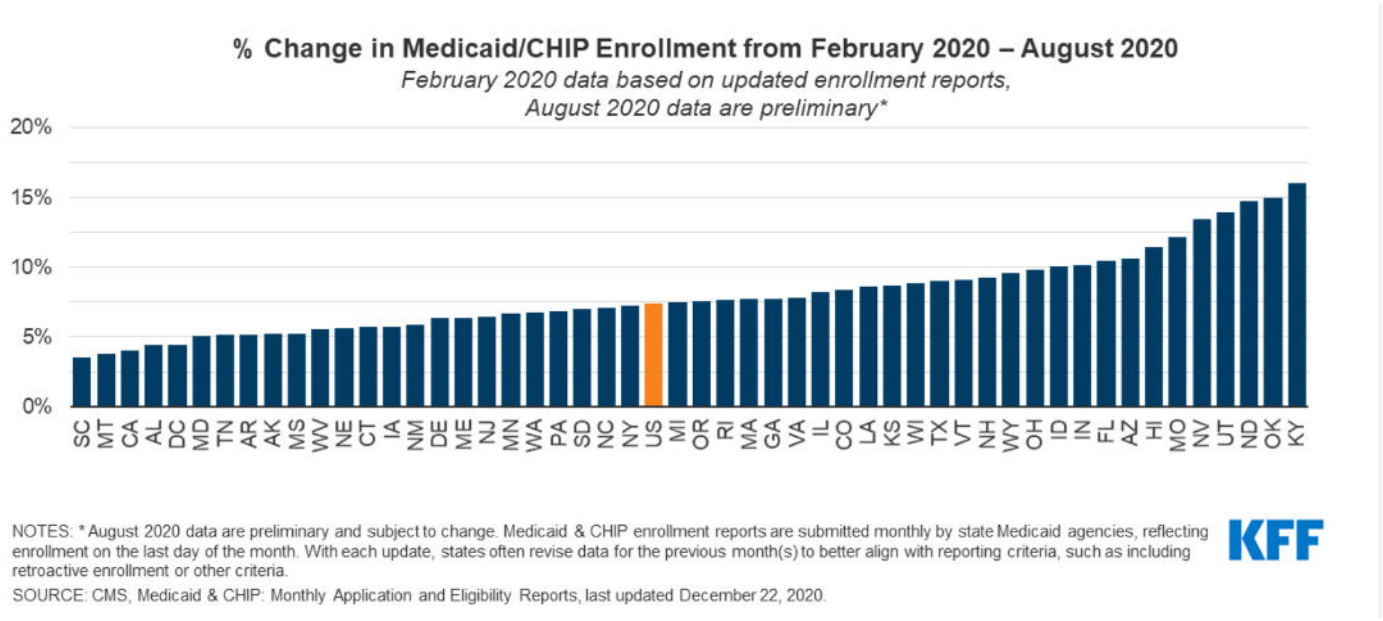
HHS and the States: Quick Guidance and New Flexibilities

As the pandemic hit, HHS provided guidance and templates for state Medicaid programs to adapt to the PHE. "Sample Disaster Relief State Plan Amendments" showed states how to use Medicaid's statutory flexibility to temporarily expand and streamline eligibility and enrollment. A Section 1115 template focused primarily on demonstration waivers during the PHE. A Section 1915(c) template provided guidance for a plethora of temporary PHE changes to enhance and support home and community-based services. And a Section 1135 Medicaid and CHIP Checklist detailed additional waiver flexibilities during the PHE.

Forty-seven states are using these emergency authorities to streamline eligibility and enrollment to connect people to coverage more quickly during the COVID-19 crisis, going beyond the MOE (Rudowitz, et al., 2020). Over half of states have expanded eligibility for seniors and people with disabilities, and a few states increased the number of home and community-based waiver slots. More than one-third have waived premium and/or cost sharing for seniors and people with disabilities (Rudowtitz, et al, 2020). These emergency authorities expire when (or soon after) the PHE ends.

Medicaid Enrollment Increases during the Pandemic

After enrollment declines in 2018 and 2019, Medicaid enrollment increased in 2020 as the pandemic grew. From February 2020 to August 2020, Medicaid enrollment grew by 5.3 million people, or 7.4% (Corallo & Rudowitz, 2020). Every state recorded enrollment increases, ranging from 4% in South Carolina to 16% in Kentucky, with both expansion and non-expansion states reporting increases at the high and low ends.



14.3. Enrollment from February 2020 to August 2020 increased in every state. Source: Kaiser Family Foundation (2020).

These Medicaid enrollment increases certainly reflect changes in the economy and job losses, but they also reflect MOE requirements and emergency authorities states used to streamline eligibility and enrollment. As CMS data shows below, even states with relatively low unemployment rates have experienced large increases in Medicaid enrollment. Advocates posit different reasons for these increases. In Kentucky, increased enrollment is credited to use of emergency authority to streamline application processes and allow self-attestation of income when documentation and electronic sources are not available. Missouri's Medicaid agency points to suspension of rigorous redetermination processes during the MOE as a key reason for its large enrollment increase.

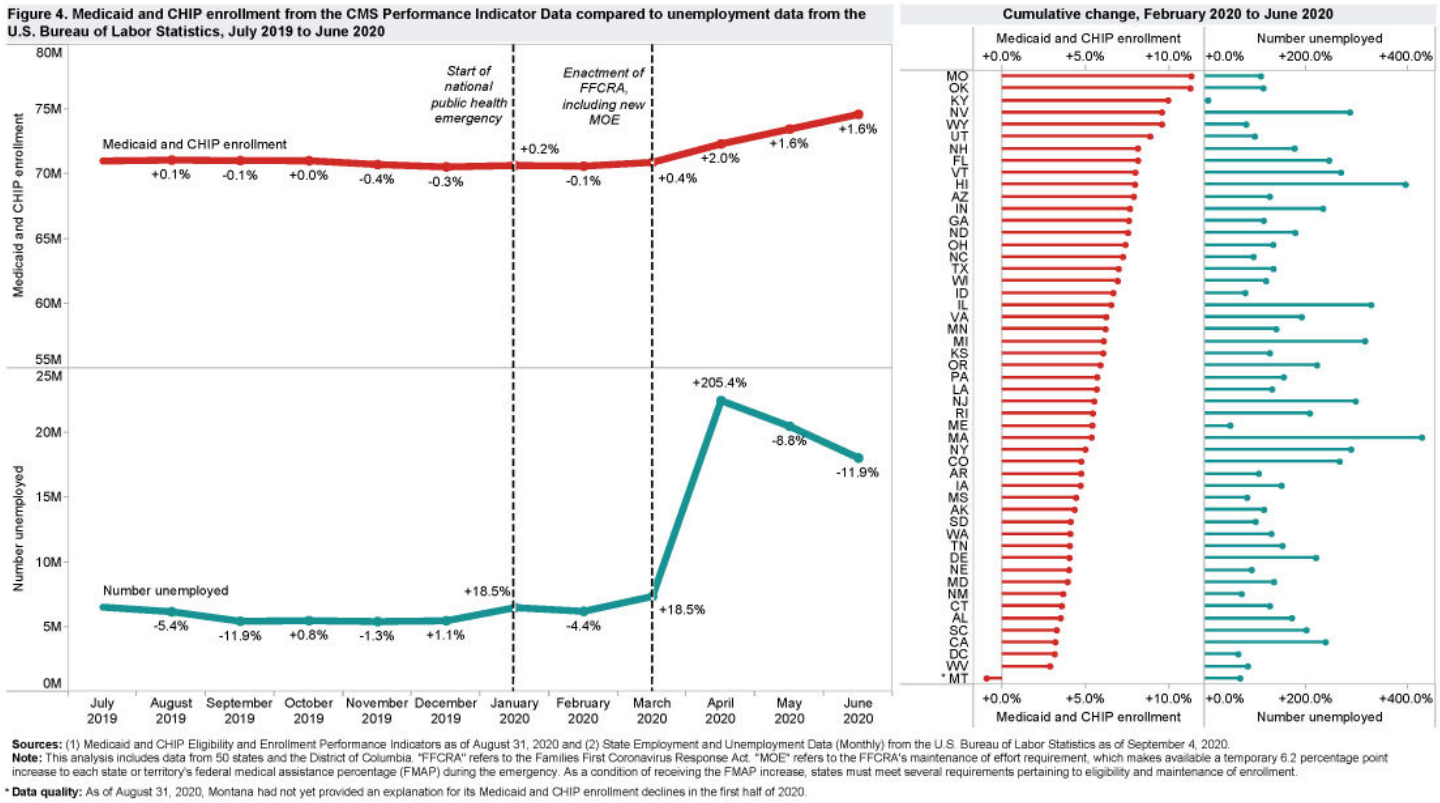
Enrollment will grow as the pandemic continues, because Medicaid enrollment typically lags behind unemployment increases (Corallo & Rudowitz, 2020). As unemployment continues to increase in 2021, even more people will become eligible for Medicaid, helping those who lose employer-sponsored coverage but also exerting pressure on state budgets.

States budgets feel strained by Medicaid enrollment increases, even with the enhanced federal match. The MOE gives states few cost constraint options, except to cut provider payments or increase cost sharing. At the urging of states, on November 23, 2020, CMS issued an Interim Final Rule (IFR) re-interpreting the Families First Act MOE requirements to, among other things, allow states to cut optional benefits like dental, vision, and outpatient rehabilitation services during the PHE. Commentators have challenged the reinterpretation, arguing it violates the letter and spirit of the Families First Act MOE requirements. With the public comment period closing in the waning days of the Trump administration, the Biden administration could adjust the rule, especially in light of largely negative public comments.

The Families First Act enhanced federal match lasts until the end of the quarter in which the PHE expires, and the continuous coverage requirement continues until the end of the month in which the PHE expires. The present PHE, renewed January 7, 2021, and effective January 21, 2021, will expire on April 20, 2021. This means the enhanced federal match will continue until at least June 30, 2021, and the MOE requirement would end on April 30, 2021. The Biden administration announced that it will continue to renew the PHE at least through January 2022. If the PHE expires while the economic impact of COVID-19 is still in full force, millions of people will remain out of work and state revenues will continue to be in crisis while Medicaid demand remains high but federal funding decreases. Therefore, the long-term economic impacts of the pandemic must be taken into account when examining how to fine-tune Medicaid's role.

Lessons Learned

COVID-19 is a stark reminder that illness disproportionately impacts low-wage workers and people of color. COVID-19 also emphasizes the vital role that Medicaid plays in providing coverage for low-wage workers and people of color. While most Medicaid enrollees are white, because of historical structural discrimination, people of color tend to work in low wage jobs and disproportionately rely on Medicaid for insurance coverage. To address health and economic disparities rendered in sharp relief by the pandemic, and to help all who lose employment during the economic downturn, the Biden administration should keep the PHE in place and work with Congress to ensure federal spending will support continued Medicaid coverage through the economic recovery. The enhanced



Sources: (1) Medicaid and CHIP Eligibility and Enrollment Performance Indicators as of August 31, 2020 and (2) State Employment and Unemployment Data (Monthly) from the U.S. Bureau of Labor Statistics as of September 4, 2020.
Note: This analysis includes data from 50 states and the District of Columbia. "FFCRA" refers to the Families First Coronavirus Response Act. "MOE" refers to the FFCRA's maintenance of effort requirement, which makes available a temporary 6.2 percentage point increase to each state or territory's federal medical assistance percentage (FMAP) during the emergency. As a condition of receiving the FMAP increase, states must meet several requirements pertaining to eligibility and maintenance of enrollment.
* **Data quality:** As of August 31, 2020, Montana had not yet provided an explanation for its Medicaid and CHIP enrollment declines in the first half of 2020.

14.4. Medicaid and CHIP enrollment from the CMS Performance Indicator Data compared to unemployment data fromthe U.S. Bureau of Labor Statistics, July 2019 to June 2020. Source: U.S. Centers for Medicare and Medicaid Services.

match provides broad fiscal relief to states and also supports increases in enrollment, continuous coverage for enrollees, and prevents states from cutting Medicaid eligibility.

The Biden administration notified states that it intends to maintain the PHE at least until January 2022. It also notified states that HHS will give at least 60 days' notice before the end of the PHE to allow state Medicaid programs time to plan their transitions. HHS should provide guidance to ensure those who are eligible stay enrolled when the PHE terminates and assist states to modify policies that expand and streamline eligibility and enrollment from emergency authorities to permanent authorities when the PHE ends.

In 11 of the 14 states that have not implemented the ACA Medicaid expansion, workers who lose their jobs and employer-sponsored health insurance coverage because of the pandemic have no safety net. In these non-expansion states (other than Wisconsin), the only working age adults who qualify for Medicaid are very poor parents, caretaker relatives, and people who qualify due to a disability. If these states expanded Medicaid, nearly four million uninsured low-income adults, including 640,000 frontline workers, could gain coverage (Straw, et al. 2021)

Biden's campaign platform included a federal "public option," federal health insurance that would cover low-income adults in non-expansion states. Enacting a public option would require a 60-vote majority in the Senate due to filibuster considerations.

However, Congress can use the budget reconciliation process to authorize a time-limited enhanced federal match to encourage opt-out states to adopt Medicaid expansion. Under the ACA, states that adopted the Medicaid expansion received 100% federal matching funds from 2014 to 2016, with the match gradually phasing down to 90%, where the match remains today. The February 2021 House committee version of the "American Rescue Plan" authorizes a two-year, 5 percentage point Federal Medical Assistance Percentage (FMAP) increase in states that have yet to expand Medicaid (Straw, et al (2021). This incentive funding is particularly meaningful as states experience higher enrollment and budgetary squeezes related to the COVID-19 related recession and may overcome those reluctant to expand for political reasons.

Additionally, HHS should develop more thorough policies specifying how state Medicaid programs report race, ethnicity, and other demographic data so policymakers, researchers, and the public can better understand the role that Medicaid plays in addressing long-standing health inequities and allow for meaningful cross-state comparisons. ACA Section 4302 provides that the secretary of HHS "shall ensure" that federally supported health care programs "to the extent practicable" collect and report data on race, ethnicity, sex, language, and disability. However, HHS has not required state Medicaid agencies to report uniform demographic data–or even consistent measures. This data is key to efforts in public health and medical care to improve health equity and plan for future emergencies.

Recommendations for Action

Federal government:

- HHS should renew the PHE declaration at least through 2021, so states continue to receive an enhanced federal match and the MOE requirements that prevent cutting eligibility and enrollment stay in place. HHS and Congress should work together to ensure that the enhanced federal match lasts through the economic recovery to relieve state budgets of the burden of continued enrollment increases while the economy improves.
- The administration should stop defending waiver approvals involving work requirements in the lawsuits before the Supreme Court and elsewhere and should revise 1115 waiver policy to encourage expanding coverage; HHS should rescind policies that limit coverage and make it clear that Medicaid exists to support low income populations; HHS should renegotiate restrictive provisions in approved waivers, and refuse renewal requests, making it plain that policies like work requirements do not promote Medicaid's objectives.
- When the PHE ends, HHS should provide guidance for states to help transition emergency policies that have maintained, expanded, and streamlined eligibility during the PHE to permanent Medicaid authorities.
- HHS should require uniform data collection, consistent with ACA Section 4302, as a condition of federal funding and Medicaid participation, so that data regarding key identifying characteristics are collected by state Medicaid agencies.
- Congress should either create a public insurance option or provide a time-limited FMAP increase as a financial incentive to encourage opt-out states to implement Medicaid expansion.

State governments:

- States should continue to use the temporary authorities that allow them to maintain or expand Medicaid eligibility and streamline application and enrollment processes during the PHE and through the economic downturn until recovery is clear.
- States should adapt these policies into permanent features when the PHE ends.

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Caring for the Uninsured

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SUMMARY. With a large uninsured population, the United States continues to depend heavily on health care safety net providers for ensuring access to essential services, in particular, vaccination services. The Consolidated Appropriations Act of 2021 provides modest funding to support health care for the uninsured, but the American Rescue Plan offered by the Biden administration promises both dramatic expansion as well as an approach to implementation that promotes equitable access to care.

Introduction

Chapter 14 in Volume I focused on the scope and underlying drivers of America's uninsured problem along with the ways in which factors associated with being uninsured — being poor and being a member of a minority or immigrant population — also contribute to elevated risk severe illness or death from COVID-19 risk status and reduced access to health care. The Chapter also reviewed key programs and sources of funding to support COVID-related health services for the uninsured.

The number of uninsured remains seriously elevated, with the lack of health insurance disproportionately affecting families with incomes below twice the poverty line ($43,920 for a family of three in 2021) and racial and ethnic minority Americans. The vast majority live in working families and 86% are working-age adults (Berchick et al., 2019). Geographically, the highest proportions of uninsured people can be found in the southern and southwestern portions of the United States, and live in states that to date have not implemented the Affordable Care Act Medicaid expansion for low-income working-age adults. Extensive research documents that the uninsured are less likely to receive necessary health care and more likely to avoid care for reasons of unaffordability — serious problems at any time, especially so in the middle of a pandemic. Some 650,000 essential workers fall into the Medicaid coverage gap (Center on Budget and Policy Priorities, 2020) and 13% of essential workers — higher than the national average — are uninsured. (Kearney & Munana, 2020). Half the uninsured have no usual source of health care, compared to 12% who have public insurance and 1% with private coverage (Garfield et al., 2019).

This update reviews policy developments related to care for the uninsured since July 2020, with a special focus on access to immunization for the uninsured population, who, as a result of poverty and elevated health and social risks, also may be vulnerable to COVID-19 in its most severe form. This is also the population most likely to work in low wage physical jobs that involve extensive contact with others, including working with vulnerable populations such as residents of long-term care facilities and people in need of home and community care. Also among this group are inmates of jails and prisons, who are especially vulnerable to COVID-19 and who, especially in the case of jail inmates with short-term stays, run the risk of carrying the virus back to the communities where they reside.

Immunizing this population will depend heavily on accessible mass immunization centers. It will also depend on health care safety net providers that focus on medically vulnerable populations, specialize in removing barriers to health and social services, are located in or serve medically underserved communities, provide free and low-cost care, and are heavily dependent on public financing.

Vaccine administration is a reimbursable expense under the Provider Relief Fund's Uninsured Program, which was established by the Trump administration in the spring 2020 using a small amount of direct health care funding allocated under a series of laws (Health Resources & Services Administration, 2021). However, the lion's share of these funds went to the Provider Relief Fund whose purpose is to support provider revenue losses more generally. But the spring 2020 Coronavirus Preparedness and Response Act, the Families First Coronavirus Response Act, and the CARES Act did not focus on the cost of nationwide immunization — vaccines, their administration, and the costs of creating and strengthening accessible health care delivery systems capable of reaching all communities.

Overview of Recent Developments

Consolidated Appropriations Act of 2021 (H.R. 133).

Enacted during the final days of the Trump administration, this massive piece of legislation (which encompasses all federal appropriations funding for FY 2021) also provides approximately $900 billion in COVID-19 relief funding. With respect to COVID-related health care generally and vaccination in particular, the COVID-19 relief portion of the legislation contains the following provisions:

- A relatively small amount ($3 billion) for the Provider Relief Fund, though none of this money is specifically allocated to the Uninsured Program; along with broader standards for calculating revenue losses;

- $30 billion in federal funding to support the purchase and administration of vaccines and therapeutics, of which $8.85 billion is allocated to the Centers for Disease Control and Prevention for further distribution to states, localities and territories ($4.5 billion) and $300 million allocated to communities with populations that are high risk and underserved, including racial and ethnic minority and rural communities.
- $22 billion to states for testing, tracing, and COVID-19 mitigation programs including $2.5 billion for targeted improvements to testing and contact tracing for underserved populations.

Beyond its COVID-specific provisions, the measure's general fiscal year 2021 appropriations provisions include funding for ongoing support to federally supported health care safety net providers such as community health centers, Ryan White HIV/AIDS clinics, providers serving people with mental illness and addiction disorders and receiving support from the Substance Abuse and Mental Health Services Administration (SAMHSA). In addition, the legislation extends through FY 2023 the special Community Health Center Fund, which accounts for 70% of all federal community health center grant funding. Importantly, the act also eliminates a scheduled $4 billion reduction in federal funding during FY 2021 for hospitals serving a disproportionate percentage of low income patients and pushes off further DSH funding cuts that would have taken place in FY 2022 and 2023 (American Hospital Association, 2020). Together, these provisions lend some basic stabilization support to health care safety net providers.

President Biden's American Rescue Plan

President Biden's American Rescue Plan provides for $1.9 trillion in new COVID-19 federal investments. Much of this funding is allocated to a variety of forms of individual financial relief for families, general relief to states, and funds to support school reopening, and other activities. However, a centerpiece of the plan is funding to support a robust national vaccination program, at an amount set at $160 billion in new funding for testing, immunization, and public health jobs. Among its most important features, the plan tackles the problem of health inequity head-on.

Immunizations. The plan proposes $20 billion for a national vaccine program, with funding to states localities, territories, and Tribal governments to open up mass immunization centers, send mobile clinics into hard-to-serve areas in order to ensure that "all people in the United States — regardless of their immigration status — can access" immunizations free of charge and without cost sharing. The plan explicitly calls for actions that will reduce the "disparities in the pandemic at every step, from ensuring equitable distribution of vaccines and supplies to expanding health care services to underserved communities."

Investment in community-based providers. To this end, and in addition to its $20 billion governmental investment, the plan calls for a direct and separate investment in community health centers, the nation's largest primary care system for medically underserved communities as well as heightened investments in Tribal health care. (The plan does not specify a recommended amount.) Thus, the plan would supplement governmental funding with a direct infusion of funds into community-based providers located in the high-vulnerability communities and serving vulnerable populations, disproportionately uninsured.

Testing. The plan calls for $50 billion in a massive scale-up of testing capacity to ensure health safety in schools and facilities housing highly vulnerable populations including long-term care institutions and prisons and jails. With respect to long-term care institutions, the plan specifically references not only residents but also the "African-American and Latina women, who have borne the brunt of the pandemic [and who] are overrepresented among long-term care workers." In the case of prisons and jails, the plan explicitly aims to protect not only prisoners but also one of the nation's most extensively community-residing uninsured populations — the formerly incarcerated as they reenter their communities.

Expanding coverage for the uninsured. President Biden's plan calls for reforms to the Affordable Care Act (ACA) Marketplace subsidy system that would broaden its protections against high-out-of-pocket premium costs for middle income families, by capping total premium costs at no more than 8.5% of income. This is a dramatic reduction in the potential financial exposure now faced by families with incomes that exceed the ACA's original upper subsidy threshold of 400% of poverty ($104,800 for a family of four) (Kaiser Family Foundation, 2020). The plan also would increase the generosity of tax credit subsidies for those with low household incomes, the precise level of increase unspecified. The plan remains silent on relief for residents of the 14 states in which the Medicaid expansion is not in effect (Kaiser Family Foundation, 2020), either because expansion has not yet been implemented or because no expansion actions have occurred. In these 14 states, more than two million people, including more than 160,000 essential workers, would remain without a pathway to affordable insurance because their incomes fall below the lower threshold for Marketplace subsidies and they do not qualify for traditional Medicaid.

Presidential Executive Orders

Beyond the American Rescue Plan, the president has issued a series of executive orders aimed at ensuring rapid executive action in accordance with presidential direction. Among these orders are:

- **Executive Order No. 13995**: Ensuring an Equitable Pandemic Response and Recovery, which focuses on mitigating the "severe and pervasive" health and social inequities that have been "exposed and exacerbated" by COVID-19. This action is to be carried out through a task force consisting of key federal agencies and outside experts and charged with, among other matters, making recommendations regarding how COVID-19 relief fund agencies can ensure equity in funding distribution and conduct outreach to communities of color and other underserved populations.
- **Executive Order No. 13997**: Improving and Expanding Access to Care and Treatments for COVID-19 that, among

other matters, aims to improve health system capacity to support both patients and workers. Under this executive order, the secretary of Health and Human Services (HHS) must specifically, through the Health Resources and Services Administration (HRSA) and the Substance Abuse and Mental Health Services Administration (SAMHSA), expand access to programs and services aimed at helping patients with long-term recovery needs. Specifically, this executive order directs HRSA to provide technical support to community health centers engaged in the COVID health care and long-term recovery effort. The order also calls for "equitable and effective distribution of therapeutics and bolster clinical care capacity where needed to support patient care" and overcoming barriers to "effective and equitable use of existing COVID-19 treatments. Specifically the order also calls for an evaluation of the COVID-19 Uninsured Program and requires HHS to "take any available steps to promote access to treatments and clinical care for those without adequate coverage, to support safety-net providers in delivering such treatments and clinical care, and to make the Program easy to use and accessible for patients and providers, with information about the Program widely disseminated."

- **Executive Order No 13985:** Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. This global order, which transcends all federal policies, aims to advance equity and support for underserved communities by "[a]ffirmatively advancing equity, civil rights, racial justice, and equal opportunity" across government as a whole. Specifically the order directs the White House Domestic Policy Council to "coordinate efforts to embed equity principles, policies, and approaches across the Federal Government [through] efforts to remove systemic barriers to and provide equal access to opportunities and benefits, identify communities the Federal Government has underserved, and develop policies designed to advance equity for those communities." Under this directive, the council is expected to conduct equity assessments across the federal government and develop, with the Office of Management and Budget director, methods for "allocating Federal resources in a manner that increases investment in underserved communities, as well as individuals from those communities."

Recommendations for Action

The first year of the federal response to the pandemic offers unequivocal lessons regarding care for the uninsured. Most clearly, the past year has shown us the extent to which the United States simply has failed to use readily available tools to ensure that — at least during a public health emergency and the recovery period that follows — all Americans are insured, that essential health services are available in medically underserved communities, and that methods are in place for ensuring that emergency resources can move quickly into the highest risk communities and be put to work.

On the eve of the pandemic, more than 30 million people lacked health insurance, and health care safety net providers already were struggling with chronic underfunding. Despite the existence of a nationwide federal health insurance marketplace that offers a ready means for supporting such a system, the nation lacked any policy that would enable uninsured people to immediately enroll in subsidized Marketplace plans. Despite the fact that safety net providers are readily identifiable through the federal funding mechanisms that provide ongoing support (such as Medicaid hospital disproportionate share hospital (DSH) payments, the Indian Health Service, grants to community health centers and other community-based safety net providers, and grant programs supporting state and local public health agencies), the nation still lacks any emergency relief fund that can be rapidly deployed to infuse resources into these providers to support expanded sites, services, and workforce. It is not that the United States lacks the knowledge regarding where to send support or even the mechanisms to move that support rapidly; it is that we have not used this knowledge or these mechanisms.

The first step is enactment of the urgently-needed American Rescue Plan, which has been designed to support a nationwide strategy for containing and eventually overcoming the pandemic in all communities, in accordance with presidential directives that aim to ensure an equitable response.

In the longer term, however, the nation needs a strategy for ensuring that in future public health emergencies — whether local, regional, or nationwide — Americans do not find themselves without resources to ensure equitable access to care. The legal mechanism for declaring a public health emergency exists in federal law, of course, and where health care is concerned, this mechanism authorizes the HHS secretary to make certain changes in federal Medicare policy and to authorize similar modest changes in state Medicaid operations. But in a nation that lacks universal health insurance, the ability to trigger emergency coverage becomes paramount. Moreover, fundamental equity considerations dictate that in times of emergency, additional, direct funding be rapidly deployed to providers serving populations and communities facing elevated risks along with serious health care shortages. The pandemic has demonstrated the essential nature of a fallback public health emergency insurance mechanism coupled with rapid deployment of additional, direct resources into medically underserved communities and populations.

Recommendations for Action

Federal government:

- Congress should revise existing federal emergency laws to provide for automatic emergency funding to specifically identified health care safety net providers for testing, treatment (including vaccines and their administration), and recovery care. At a minimum, such identified providers should include federally-funded community health centers and "look-alike community health centers" designated as such for purposes of Medicare and Medicaid "federally qualified health center" payments, "deemed" DSH hospitals, Title X family planning providers, the Indian Health Service, rural hospitals designated as critical access hospitals, rural health clinics, state and local health agencies, and other providers designated by the HHS secretary as essential providers during public health emergencies.
- Congress should create a universal insurance coverage mechanism to ensure access to coverage during a declared public health emergency. Such an emergency coverage mechanism should be open to any person who lacks health insurance covering testing, treatment (including immunization), and post-emergency recovery services. Coverage should encompass both treatment for conditions caused by the emergency, as well as underlying conditions exacerbated by the emergency or that could delay or complicate recovery. The establishment of a national exchange system makes this type of emergency insurance feasible through the use of a special enrollment period linked to public health emergencies. This is essentially the model that the Biden administration is now effectively testing on a limited scale under Executive Order 14009. However, that executive order can make affordable insurance available only to people who qualify for subsidized coverage under ACA rules (those with incomes between 100% and 400% of the federal poverty level (between $21,960 and about $88,000 for a family of three in 2021), since the president lacks the power to expand the subsidy system to all Americans without an act of Congress.
- In order to relieve the extraordinary financial pressures states face during public health emergencies, Congress should establish a special emergency-related increase in the Medicaid "federal medical assistance (FMAP)" formula that would increase all state FMAP rates to 90% for all program costs for the duration of the emergency and recovery period.
- The Biden administration should develop model demonstration programs under Medicaid and the Children's Health Insurance Program that permit states to extend Medicaid to all uninsured low income residents and that waive normal budget neutrality principles for the duration of the emergency and recovery periods.

State governments:

- Governors and state legislatures should devote additional resources to support uncompensated care costs through direct grants and should accompany such direct funding with a temporary upward adjustment to Medicaid provider payments.
- Governors and state legislatures should make readiness grants available to help safety net providers immediately begin the process of adapting to operating in emergency conditions, including resources to help providers locate, secure, and expand into additional operating sites and expanded hours, bring on additional staff, and secure needed equipment and supplies. These emergency response grants should also support activities such as contact tracing, outreach and patient support services, and temporary housing and living supports for staff, and housing support for homeless patients and people too sick to return to their residences.
- Governors and state legislatures should establish mechanisms that will immediately expand support to state and local health agencies to rapidly deploy supplemental public health professionals to develop and implement emergency response plans and provide technical support to local health care efforts.

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Telehealth and Inequity during the COVID-19 Response

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SUMMARY. The COVID-19 pandemic has accelerated the use of telehealth to improve health care access and promote social distancing. However, telehealth introduces new challenges and barriers for health care access, particularly where patients are responsible for initiating a telehealth encounter without a facilitating provider (e.g., a health clinic as an originating site). A successful telehealth encounter requires capable technology, reliable high-speed internet, and sufficient digital literacy to use telehealth software. In addition to these telehealth-specific barriers, traditional health care barriers, such as cost, coverage, cultural competence, and disability, can be compounded or amplified by the confluence of telehealth and the impacts of COVID-19. Unfortunately, these barriers are disproportionately experienced by many populations that already face disparities in COVID-19 burden and risk. As such, health care disparities and inequities could widen for some populations with an increased focus on telehealth during the COVID-19 response. This Chapter supplements the recommendations provided in the first Volume with additional recommendations intended to address telehealth disparities and inequities including funding for community health workers to educate and train patients for telehealth services and subsidizing technology and internet access needed for telehealth services.

Introduction

Telehealth is a tool that improves health care access by connecting patients with distant providers (HRSA, 2018; Speyer et al., 2018). More recently, it has been used as a tool to promote physically distant care to protect providers and patients from COVID-19 infection (Schmit et al., 2020). In this way, telehealth addresses a singular, but critical, health care barrier: access to availability of health care services. A number of different factors determine the availability of health care services to a particular patient. For example, a patient in a rural area might be far from an available provider. Similarly, a patient might not have access to transportation to reach an available provider or available transportation (e.g., public transit) is prohibitively difficult or time consuming to use to access needed health services. During the COVID-19 pandemic, these barriers to health care services are compounded by safety concerns, like risk of transmission in provider offices or on public transportation. The effective use of telehealth in these situations can facilitate access to health care services while mitigating safety risks (Schmit et al., 2020)

However, telehealth does not eliminate all barriers to health care access. In fact, telehealth introduces new barriers to health care services (Nouri et al., 2020). In traditional health care, a patient needed a mode of transportation (e.g., a car), a way to travel (e.g., roads), and knowledge of how to get there. In telehealth applications, these barriers are swapped for new barriers: access to a telehealth-capable device, access to high-speed data transmission, and digital literacy (Velasquez & Mehrotra, 2020). A person without a telehealth-capable device (e.g., smartphone or computer with webcam) cannot access telehealth services. Similarly, a person cannot access telehealth services without access to reliable high-speed internet regardless of whether or not they have a telehealth-capable device. Moreover, telehealth can be challenging for those who are not comfortable with new technologies, have difficulty communicating on digital platforms, or do not have strong technical skills. While telehealth has no doubt made health care services more convenient for digitally-capable people with adequate technology and reliable internet in the COVID-19 pandemic, telehealth remains out of reach for many without these luxuries (Nouri et al., 2020; Hirko et al., 2020).

Unfortunately, many of the same individuals that previously faced health care access barriers, face these new barriers when accessing health care services through telehealth. (Nouri et al., 2020; Katzow et al., 2020). For example, elderly people, people of color, and individuals with low economic status all experience disproportionate challenges with access to telehealth-capable technology, digital literacy, and reliable internet coverage (Velasquez & Mehrotra, 2020). Notably, the populations facing disproportionate telehealth barriers also face disproportionate burden and risk of COVID-19 (Velasquez & Mehrotra, 2020). Moreover, these populations also face disproportionate barriers to

traditional health care including transportation, cost, health care coverage, language barriers, and lack of culturally competent care.

Importantly, telehealth does not solve all barriers to health care access. The majority of governmental actions promoting telehealth have focused on supply-side barriers such as restrictions on provider types (e.g., nurse practitioners, occupational therapists, mental health professionals), and modalities (e.g., asynchronous, audio-only, secure messaging) (Schmit et al., 2020). Government interventions addressing these supply-side barriers are intended to promote telehealth delivery. Fewer governmental actions have focused on demand-side barriers, such as cost, location restrictions, and technology access. As health care providers shifted toward telehealth-only care, it is clear that many patients benefited from the expanded availability of convenient health care appointments from the comfort or safety of their homes. However, other patients experienced new and sometimes exacerbated barriers as in-person health care transitioned to telehealth modalities in the COVID-19 environment (Nouri et al., 2020). These exacerbated barriers are likely to be the most pronounced with telehealth services provided in a patient's home, where the patient is responsible for acquiring needed technology, establishing a suitable network connection, and operating the telehealth application independently.

Existing Health Care Barriers Compounded by Telehealth and COVID-19

Cost and Coverage

Health care services are expensive, and individuals without health care coverage or with limited resources often face difficult budgeting decisions between competing essential needs (e.g., groceries, rent, health care) (Healthy People, 2020). Several state and federal actions in response to COVID-19 were intended to address costs but were limited in their scope. For example, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) contained provisions limiting patient costs, but these provisions were limited to COVID-19 testing and treatment. Additionally, several states took emergency actions to limit out-of-pocket expenses for telehealth services for those with health care coverage (Schmit et al. 2020). However, generally patients making decisions about whether to see a provider for a health concern during the COVID-19 pandemic still face the same cost challenges as they did prior to the pandemic. Moreover, a patient that needs to utilize telehealth faces additional costs (e.g., telehealth-capable device, high-speed internet).

Related to cost, the lack of heath care coverage is a substantial barrier to health care services. People without health insurance face long-term financial consequences from an unexpected health condition (Healthy People, 2020). This often results in delayed care for uninsured persons, and worsening of existing conditions (Stop TB Partnership, 2020). COVID-19 has exacerbated this existing barrier by creating dire economic conditions resulting in lost employment, and consequently, lost employment-based health coverage. Health care coverage can be further magnified as a barrier if health care systems and providers focus scarce telehealth capacity on patients with health care coverage that provides the most lucrative reimbursement rates (i.e., private insurance) (Clair et al., 2020).

Telehealth has additional coverage challenges. As an emerging health care innovation, insurers reasonably were skeptical of the comparative quality of telehealth services as compared to similar in-person services. This initial skepticism resulted in health care coverage policies that provided less coverage and reimbursement for telehealth services than similar in-person services. Since then, federal and state governments have gradually enacted laws and policies that have required health plans to provide comparable coverage and reimbursement for telehealth services to the similar in-person service (CCHP, 2020; Schmit et al., 2019). This coverage expansion accelerated tremendously in response to COVID-19 (Schmit et al., 2020). Nevertheless, regulatory inertia — affected by political will, available resources, external influences, etc. — means that telehealth coverage still lags behind traditional in-person services. Consequently, coverage barriers are increased for people needing telehealth services.

Cultural Competence

Cultural competence is essential for productive provider-patient relationships and successful treatment outcomes (Healthy People, 2020). Cultural competence fosters patient trust and enables providers to understand the specific context, lived experience, and environmental conditions that shapes the lives, and ultimately, the health outcomes of their patients. Telehealth has potential to promote cultural competence because it allows providers a limited window into the lives (and perhaps homes) of their patients. However, telehealth also leaves a physical (and emotional) distance between the provider and patient. This distance can obscure social and cultural cues, slow the development of trusting relationships, and fortify a provider's inherent biases that contaminate treatment decisions. Consequently, telehealth creates some additional challenges for culturally competent care. Community health workers are especially well-suited to address cultural barriers due to their specialized knowledge of the communities they serve and have promising potential to assist with telehealth education and training (Velasquez & Mehrotra, 2020).

Language

Language can be a substantial barrier to health care access (Healthy People, 2020; Katzow et al., 2020). Beyond the substantial and consequential difficulties that can result from language differences between the provider and the patient, language can be a substantial barrier to navigating the health care system generally. For example, a non-English speaker might have difficultly identifying a provider and making an appointment.

Language is a pronounced barrier for telehealth encounters (Katzow et al., 2020). In addition to navigating the health care system, patients need to learn how to use the telehealth platform, which can be difficult for non-English speakers in the United States (who might also have digital literacy challenges). Additionally, interpretation services must be available to facilitate the health care encounter and facilitate patient understanding of

the prescribed treatment. While interpretation services can be integrated into a telemedicine encounter, doing so requires the provider has established those processes and workflows. Given the rapid transition to telehealth and strain on the health system due to COVID-19, developing the processes and workflows for interpretive services is not trivial. In the meantime, language barriers to health care access are magnified.

Disability

Telehealth brings both benefits and challenges for people with disabilities. Telehealth has substantial potential to improve health care access to persons with disabilities that create travel challenges for in-person health care appointments (Noel & Ellison, 2020). In those cases, telehealth care eliminates the barrier by facilitating the health care encounter in a convenient location (especially if at the patient's home). However, telehealth cannot address all barriers to health care access for people with disabilities. The disabled community is diverse and health care access challenges can be highly unique given the nature of a person's disability. Moreover, people with disabilities face a technological disparity in that they are less likely to own a computer and less likely to be online (Noel & Ellison, 2020). Consequently, these technological disparities threaten to widen the existing health disparities for persons with disabilities as COVID-19 forces health care encounters to telehealth modalities.

Additional Barriers for Telehealth Services

Technology Access

Telehealth requires a telehealth capable device and reliable internet coverage (Velasquez & Mehrotra, 2020; Nouri et al., 2020). Both of these requirements are significant costs particularly in the challenging economic environment caused by COVID-19. Life-changing events precipitated by the COVID-19 pandemic can cut a person off from the internet. The loss of a job, an eviction, or the closing of a local library can mean the loss of a computer used for online access. Individuals without a telehealth-capable device may be spared a co-pay by state or federal law, but cost of a new computer or smartphone is a much steeper entry requirement.

Federal and state actions in response to COVID-19 have sought to ameliorate technology access issues by authorizing new modalities of telehealth delivery, including "store-and-forward" asynchronous communications, audio-only (i.e., telephone) communication, and secure messaging (e.g., text, email). Previously, real-time interactive (i.e., synchronous) video communication was the dominant and preferred mode of telehealth delivery for quality health care encounters (CCHP, 2020; Schmit et al., 2019). Expanding telehealth services to include new modes of delivery that could be used by individuals with limited technology access certainly helped persons access needed services who would otherwise be cut off from health care during COVID-19 restrictions. Some care is better than no care (Schmit et al., 2020).

However, governmental efforts authorizing inferior modes of telehealth do not fix the inequities that result from unequal technology access. In fact, normalizing inferior modes of health care services (i.e., audio-only telehealth), only serves to bake unequal treatment into the system for those with fewer resources, ultimately leading to wider inequities in health care outcomes.

Addressing the technology access barrier is an immense challenge in the COVID-19 pandemic. Adding new community resources (e.g., publicly accessible library computers) create new opportunities for spreading the virus in the community. Addressing technology barriers while limiting opportunities for COVID-19 spread requires an individualized (i.e., expensive) intervention. For example, federal individual stimulus payments can be used to adopt the technology needed for telehealth (as well as remote work) during the pandemic. However, previous stimulus payments are likely to have been too little to provide much more than basic sustenance for those in need (i.e., food, utilities, rent), much less telehealth-capable technology.

Broadband Access

Similarly, regular payments for high-speed internet services are a luxury for many families in the present environment. With families making difficult decisions about groceries, rent, and utilities, the sustained cost for internet access can be an increasing burden. Utility cut-offs and evictions can abruptly eliminate previously available internet access. Additionally, previously available Wi-Fi hotspots have become more limited as businesses have reduced capacity, cut operating times, or closed (Lawton, 2020). Given the cost-savings associated with telehealth combined with the potential savings associated with preventing more costly services (e.g., emergency room visits) with early intervention, there is a fiscal argument for providing support for broadband access as a means to enable telehealth services (Nord et al., 2019). This fiscal argument is particularly strong for patients with chronic conditions and high utilizers of health care services during the COVID-19 pandemic, where many health conditions may be neglected as a result of current difficulties (e.g., economic constraints, physical distancing).

The federal CARES Act contained substantial funding, including providing $200 million to the Federal Communications Commission, to improve broadband infrastructure and funding to address telehealth technical barriers (Schmit et al., 2020). Much of this funding has gone to expand broadband access, especially in rural areas, as well as supporting public Wi-Fi access (e.g., libraries), and improving connectivity in clinics for telehealth services (e.g., Federally Qualified Health Centers) (Pew Charitable Trusts, 2020). While expanding available free Wi-Fi locations improves access, it is not a perfect solution. Public Wi-Fi locations create additional risks for viral spread, and raise privacy concerns for telehealth appointments (i.e., eavesdropping). More recently, Section 904 of the Consolidated Appropriations Act of 2021 created the Emergency Broadband Connectivity Fund and the Emergency Benefit Program that provides a monthly discount for broadband internet access and equipment during the COVID-19 response. As a discount, these programs help individuals that can afford standard internet connectivity upgrade to broadband, but it will have limited utility to those who cannot afford internet as an additional monthly expense. Still, the Emergency Broadband Connectivity Fund provides a new tool to address broadband access disparities.

Digital Literacy

Digital literacy is a barrier to telehealth services that is disproportionally felt by some populations, particularly for the elderly, people of color, and individuals with low socioeconomic status (Velasquez & Mehrotra, 2020). Utilizing telehealth requires comfort with technology, including operating the device (e.g., smartphone, computer) and navigating required applications (Katzow et al., 2020). A new telehealth encounter might require a patient to become familiar with a provider's online patient portal to find appointment details and instructions. Telehealth patients might also need to identify, download, install, and operate a new telehealth application, which might differ between different health care providers. When patients have substantial technical difficulties, appointments can be missed, cut-short, or converted to a less than ideal format (e.g., phone) (Crawford, 2020). Since these challenges are disproportionally experienced within certain populations, continued reliance on telehealth as a dominant form of health care delivery risks widening inequities among these populations without adequate care or intervention (Velasquez & Mehrotra, 2020; Katzow et al., 2020).

Inequities and Disparities Compounding Telehealth Barriers

Inequities and disparities can be substantial barriers to health care access generally, but these disproportionate impacts are not felt in a vacuum. COVID-19 hit health systems, social structures, and economic sectors with existing disparities and inequities. Accumulating evidence shows that COVID-19 disproportionately affects certain populations through increased health risk as well as economic and social harm. Perhaps unsurprisingly, the populations that are hit the hardest by COVID-19 are many of the same populations that experience the most significant economic, social, and health inequities (Artiga et al., 2020).

These existing inequities and disparities contribute to barriers for telehealth services. The lack of education can contribute to digital literacy. Unemployment, underemployment, and low wages limit resources available for telehealth-capable technologies and high-speed internet. Consequently, the same populations that might have the highest need for health care services also experience substantial barriers to receiving telehealth services (Nouri et al., 2020; Velasquez & Mehrotra, 2020). As a result, telehealth's value as a tool to promote health care access is inequitably limited for many disadvantaged populations.

Telehealth as a Health Care Access Solution

Without question, telehealth is a tool that promotes access to health care, reduces health care costs, and promotes the physical distancing necessary to slow COVID-19 transmission (Schmit et al., 2020). Telehealth can be an extremely convenient option for individuals who have a telehealth-capable device, like a smartphone or computer with a webcam, a reliable high-speed internet connection, and have good digital literacy. For these individuals, telehealth is an effective, convenient and cost-effective option (Nord et al., 2019).

However, telehealth is not a panacea for all health care access barriers. Existing barriers, such as cost, coverage, cultural competence, language, and disability might remain despite a telehealth care option. Moreover, if telehealth is the dominant available option, these existing barriers can be amplified for some patients (Katzow et al., 2020). Additionally, telehealth creates new barriers that can be substantial for some patients. A telehealth encounter requires sufficient technology, network connection, and user knowledge to be successful (Velasquez & Mehrotra, 2020). These requirements can impede health care access where patients are expected to independently connect with providers (i.e., without a facilitating provider).

Most concerning is that these telehealth barriers are experienced disproportionately by populations already experiencing significant disparities and are facing high-risk for COVID-19 exposure and harm (Kaiser Family Foundation, 2020). As such, the convergence of disparities and telehealth access barriers will likely lead to widening inequities if not addressed. Indeed, a substantial drop in the proportion of at-risk populations (i.e., older adults, people of color, and individuals with low socioeconomic status) receiving telehealth services was observed in the early months of the COVID-19 response (Nouri et al., 2020). The reality is that telehealth is a tool with clear entry requirements. To the extent patients bear the burden of these entry requirements, telehealth will remain a tool for the privileged (Katzow et al., 2020).

Recommendations for Action

The previous Volume provided numerous recommendations to promote the use of telehealth during the COVID-19 pandemic and beyond. The recommendations below are intended to supplement those prior recommendations.

Federal government:

- Congress should authorize Medicare and Medicaid reimbursement for community health workers providing patient training and education relating to telehealth and encourage providers to target populations with known disparities in telehealth services.
- Congress should authorize technology and broadband subsidies (such as those in the Emergency Broadband Connectivity Fund) for high utilizers of Medicare and Medicaid programs to enable preventive health care services during the COVID-19 pandemic.
- The Department for Health and Human Services and the Centers for Disease Control and Prevention should monitor inequitable outcomes associated with telehealth policies and practices, especially in vulnerable populations.

State governments:

- State legislatures should provide funding for community health workers to provide telehealth training and education to vulnerable populations.
- State legislatures should provide technology and broadband subsidies for high health care utilizers and vulnerable populations to enable preventive health care services during the COVID-19 pandemic.

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Assuring Access to Abortion

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SUMMARY. Over the spring of 2020, numerous states announced measures suspending abortions in response to COVID-19. Banning abortion during the pandemic proved counterproductive. Not only did bans fail to preserve health care resources, prohibiting access to abortion care exacerbates the strain on the health care system. People who lack access to abortions will travel to neighboring states, induce their own abortions, or carry pregnancies to term. More importantly, the people hit hardest by suspending abortion care are those for whom the pandemic already has had devastating effects. Lifting legal restrictions on medication abortion, and expanding telehealth abortion services specifically, can conserve health care resources and reduce unnecessary provider-patient contact. To these ends, in July 2020, a federal district court enjoined a U.S. Food & Drug Administration restriction, for the duration of the pandemic, that requires in-person collection of the first drug (mifepristone) of the medication abortion regimen at a health care facility. However, the Supreme Court stayed the injunction pending the appeals process. In addition, eight states carve out exceptions for abortion in their telemedicine policies, and 19 states require in-person administration of abortion services, thereby prohibiting remote care indirectly. The result is a country divided by legal permission for teleabortion: around half of states permit remote care and the other half prohibit it. Policymakers and executive officials can eliminate barriers to safe abortion services now and in the future. Although not without limitations, telehealth for medication abortion can ease the burdens on pregnant people, health care workers, and health systems in light of the unprecedented challenges presented by COVID-19.

Introduction

Abortion law and policy has been in flux since the beginning of the pandemic. In March 2020, 12 states suspended abortion care, for differing lengths of time, in response to COVID-19 (Sobel et al., 2020). State officials argued that the policies classifying abortion as a nonessential surgery reduced patient-physician contact as well as preserved medical supplies, hospital space, health care capacity. All but two appellate courts were unpersuaded by these arguments. Federal district courts in six states issued injunctions of the orders after holding that the bans violated patients' constitutional right to an abortion, ignored medical evidence of the short-term and long-term consequences of delayed abortion care, and exacerbated the public health emergency by ultimately increasing pregnant people's use of health care systems.

Around the same time, telemedicine for medication abortion care expanded over the summer and fall of 2020. Medication abortions make up almost 40% of the nation's total abortions (Jones et al., 2019). In a medication abortion, which occurs during the first 10 weeks of pregnancy (or 11 weeks for off-label but accepted use), patients ingest two pills: the first drug, mifepristone, is followed by a second drug, misoprostol, taken 24 to 48 hours later. Extensive research demonstrates that medication abortion, like many other health care procedures, can be safely and effectively administered online or over the telephone. In July 2020, a federal district court held that the FDA's requirement that mifepristone, the first drug administered in a medication abortion, must be collected at a hospital, medical office, or clinic was unconstitutional while the pandemic lasts. As a result of the district court's decision, patients living in states that do not require in-person collection could receive counseling online and medication abortion by mail. The expansion of remote care for abortion, however, slowed when the Supreme Court stayed the district court's injunction in January 2021.

Given the challenges still presented by COVID-19, state and federal policy should permit teleabortion to the extent it is feasible, and suspend medically unnecessary requirements, such as in-person counseling, that increase clinic-patient contact. Enabling remote access to abortion would ease the already heavy burdens that fall disproportionately on low-income people and people of color, and thwart state attempts to further eviscerate abortion rights. To that end, the Biden administration should suspend the FDA's in-person requirement, removing the unnecessary impediments to progress erected by the Supreme Court. In the same vein, states should encourage the expansion of telehealth, which includes medication abortion.

State Abortion Care Suspensions

In March and April of 2020, 12 states issued executive orders and public health directives that either implicitly or explicitly suspended most (and in one state, all) abortion services during the COVID-19 emergency. In all but two states, these policies were

enjoined by courts, lifted after settlements with state officials, or expired when executive orders expired. (For more information on state abortion bans, see Chapter 15 in *Assessing Legal Responses to COVID-19: Volume I*).

The executive orders of five states (Alabama, Ohio, Oklahoma, Tennessee, Texas), issued by the governor or the state's public health department, were enjoined by federal district courts, which held that either the suspension of non-essential services did not apply to abortion or the bans contravened the constitutional right to abortion before viability. Texas is distinct among these five states because its legal path was particularly twisting; a federal appellate court ultimately enjoined the ban in part.

The Texas attorney general applied the Governor's order mandating all licensed health care professionals postpone surgeries and procedures not immediately medically necessary to all abortion care — surgical and medication — unless there was a threat to the life of the pregnant person. In late March 2020, the U.S. District Court for the Western District of Texas granted a temporary restraining order, which the Court of Appeals for the Fifth Circuit reversed. The Fifth Circuit held that Texas's abortion ban was a reasonable way to conserve medical supplies and hospital capacity, even though medication abortion requires no gown, mask, eyewear, shoe covers, or gloves; is not administered in a hospital or physician's office but in standalone clinics; and rarely results in a complication that would require a hospital bed (Upadhyay & Grossman, 2019). The Fifth Circuit, on the other hand, determined that delivering medication abortion requires personal protective equipment because of the pre-termination ultrasound and in-person consultation required of all abortions by Texas law. The district court granted a second temporary restraining order, permitting medication abortion and abortion for patients nearing the state's gestational legal limit. After another round of opinions, the Fifth Circuit reversed again, which resulted in the resumption of the abortion suspension with one exception. The revived suspension was short-lived; two days later, the governor's office issued a statement that abortion was excluded from a new order's terms.

Seven states (Alaska, Arkansas, Iowa, Kentucky, Louisiana, Mississippi, West Virginia) issued orders that expired or were replaced. The Arkansas order lasted longer than the others. From April 10, 2020, until June 1, 2020, the Arkansas Department of Health banned surgical abortions except if necessary to protect the life or health of the patient. The U.S. District Court for the Eastern District of Arkansas granted a temporary restraining order, but the Court of Appeals for the Eighth Circuit reversed it. The Eighth Circuit held that suspending abortion was a reasonable means to conserve hospital space and PPE, adopting the Fifth Circuit's reasoning. The state issued a modified order allowing access to abortion services if patients had at least one negative COVID-19 test within 48 hours (then, as modified, 72 hours) prior to the procedure. The testing requirement was lifted on June 12, 2020, when the order expired.

During the weeks of fluctuating legal status across these states, patients had their appointments cancelled with a moment's notice and were turned away from clinics (Alexandria, 2020). Clinics that reopened had lengthy waiting lists for appointments. The resulting hardships of state abortion suspensions, affirm that, for patients with delayed or denied care, abortion is an essential health care service.

Strain on the Healthcare System and Deepened Disparities

What state suspensions made clear was that abortion restrictions do not conserve scarce medical resources and do not impede COVID-19's spread. To emphasize what may be obvious, during the pandemic, people who travel for abortion care cannot limit social contact and take risks that could be avoided but for their state's animus for abortion rights. Many people who lack access to abortion will travel to other jurisdictions to end their pregnancies, consuming the same medical resources but requiring providers in neighboring states — without the assistance of additional staff or capacity — to manage an influx of new patients (Bearak et al., 2020). As a consequence, wait times and crowding increased at clinics in states neighboring those with abortion suspensions. Increased delay results in more expensive and invasive procedures later in pregnancy or timing out of a legal abortion altogether. In Texas, for instance, according to a recent study, the abortion rate declined by 38% during April 2020 (White et al., 2021).

People who did not or could not travel might terminate pregnancies by ordering online one or both of the pills taken in a medication abortion and taking them without physician supervision. Self-managed abortion can be effective and safe. However, it can also increase costs for the health care system if patients lack accurate information and adverse health consequences occur.

Finally, and perhaps most significantly, continuing a pregnancy requires prenatal care that includes multiple interactions, each necessitating PPE, with health care professionals — far more PPE, hospital space, and health care professionals' time than any type of abortion. Furthermore, childbirth has steep costs and health risks, particularly for low-income people and people of color. The United States has the worst maternal mortality rate in comparison to countries similarly situated; Black women are four times as likely to die in childbirth than white women (Foster, 2020).

As the pandemic has raged, health disparities have become only more pronounced. Abortion suspensions fall disproportionately on people who have shouldered the hardships imposed by COVID-19 — people who are unemployed or essential workers, and those who do not have access to health care or face other logistical challenges. Expanding access to medication abortion, particularly through telemedicine, is one means to help slow COVID-19's spread and close resource gaps. The case, *American College of Obstetricians & Gynecologists (ACOG) v. FDA*, addressed just that issue by lifting a nationwide requirement that patients collect medication abortion at a healthcare facility — progress now thwarted by the Supreme Court's order staying the injunction. And as the next section makes plain, longstanding state and federal regulation, which contradicts medical evidence and clinical practice, continues to make delivering medication abortion needlessly difficult.

The Battle over Remote Abortion Care

Abortion has been more closely regulated than comparable (and riskier) outpatient procedures long before COVID-19 (Jones et al., 2018). Specifically, state legislation has targeted medication abortion to undermine abortion rights rather than ensure patient safety, during the pandemic or before it. On the contrary, medication abortion could require no contact with health care providers for most patients, except that law requires it.

Legal Restrictions on Telemedicine for Abortion

Despite the ease with which medication abortion can be administered, and its proven effectiveness, nearly half of the states and the federal government obstruct efforts to provide remote solutions for its delivery. The FDA restricts mifepristone under a drug safety program — a Risk Evaluation and Mitigation Strategy, or REMS. When FDA concludes that REMS requirements are insufficient to protect patient safety, it can also issue an Elements to Assure Safe Use (ETASU), which can circumscribe distribution and limit who can prescribe a drug and under what conditions. The FDA mandates, among other requirements, collection of mifepristone at a clinic, physician's office, medical center, or hospital. The dominant interpretation of the ETASU is that certified providers may not dispense mifepristone through the mail or retail pharmacy.

Several states' laws impose additional restrictions in accord with or beyond FDA restrictions. Nineteen states mandate that the prescribing physician be physically present (LawAtlas State Abortion Laws, 2019). Eight states ban telehealth through legislation that exempts abortion from any permitted telemedicine. In addition, 33 states prohibit non-physicians from administering medication abortion despite evidence that advanced practice clinicians can safely and effectively counsel patients. These restrictions layer on top of additional legal requirements, such as mandatory pre-termination ultrasounds and in-person counseling.

So, while the clear trend is to extend telemedicine generally through state orders and legislation, abortion continues to receive exceptional treatment. The same is true on the federal level. In 2020, the federal government expanded telehealth for non-abortion medical services. The coronavirus relief legislation issued guidelines for Medicaid and Medicare coverage of telehealth and included grants to develop telehealth practices for federally qualified health centers, rural health clinics, and hospices. Yet last year, Congress considered the Teleabortion Prevention Act, which would require that physicians be present during terminations.

Support for Telemedicine for Abortion

A study launched by Gynuity Health Projects (with FDA permission through an Investigational New Drug Approval) assesses the efficacy of providing medication abortion care by videoconference and mail. Providers counsel patients through videoconferencing, and patients confirm gestational age with blood tests and ultrasounds at a location of their choosing. During the pandemic, patients who are not at risk for medical complications, are less than eight weeks pregnant, and have regular menstrual cycles may not need blood tests or ultrasounds. Results of the study indicate that "direct-to-patient telemedicine abortion service was safe, effective, efficient, and satisfactory" (Raymond et al., 2019). Embracing this evidence, several states have protected access to abortion through executive orders, encouraging an increasing number of health centers to adopt teleabortion methods (Baker, 2020).

The case suspending the ETASU for collecting medication abortion — *ACOG v. FDA* — is presently is before federal courts. On July 13, 2020, the U.S. District Court of the District of Maryland issued a nationwide injunction of in-person requirement for the duration of COVID-19 national emergency. The court noted that the FDA's restriction contradicts substantial evidence of the drug's safety and singles out mifepristone without any corresponding health benefit. Of the thousands of drugs regulated by the FDA, and the 17 subject to the same ETASU, mifepristone is the only one that patients must retrieve at a medical center but may self-administer without supervision. The FDA further permits mailing the same compound, when not prescribed for abortion or miscarriage, to patients' homes in higher doses and larger quantities.

The decision also details the cumulative effects of abortion restrictions based on expert testimony and public health research. The court cited evidence of how the in-person requirement exacerbates the burdens already shouldered by those who work essential jobs or are unemployed, have lost health insurance, live in multi-generational homes, and lack transportation. The opinion highlighted that low-income patients and people of color suffer disproportionately; they are more likely to become ill, to have inadequate resources to respond to illness, and will have worse health outcomes as a result deep health inequalities.

The FDA appealed the district court's decision to the U.S. Court of Appeals for the Fourth Circuit, and petitioned the Supreme Court for a stay of the injunction in October and again in December 2020. Again before the district court, the briefs filed by the solicitor general and ten states strain credibility, contesting that in-person collection imposes heightened risks for patients. States like Arkansas, which suspended abortion under the guise of protecting people from COVID-19, claimed that the pandemic poses only a minimal threat for people seeking abortion care. The government argued that mask mandates, increased testing, and better treatment have recently "mitigated or resolved any burdens" on travel, finances, or childcare, as well as eliminated risks of contraction (Solicitor General Brief to U.S. District Court of the District of Maryland, Case 8:20-cv-01320-TDC, Nov. 11, 2020).

The government's position was that remote medication abortion is a health risk, but COVID-19 contraction is not. ACOG replied with the obvious rejoinder: "the day Defendants filed their motion, approximately 100,000 people in the United States were diagnosed with COVID-19 — a new global record — and nearly 1,000 people died from it" (Plaintiff Brief in Opposition to Defendants' Renewed Motion to Stay the Preliminary Injunction, at 1, No. 20-1320-Tdc, Nov. 13, 2020). Not only has COVID-19 remained deadly, but the FDA had produced no evidence or expert to prove that the injunction had caused harm to any patient.

The district court refused to lift or narrow the injunction in December 2020, relying on extensive evidence and public health expertise. The Supreme Court, however, was not persuaded by the same factual record. In January 2021, the Court stayed the district court's injunction pending appeal. Justice Sotomayor wrote a strong dissent, which relied heavily on the district court's findings, calling the FDA's exceptional treatment of medication abortion "unnecessary, unjustifiable, irrational" and "callous" (*Food & Drug Administration v. American College of Obstetricians & Gynecologists*, 2021). The case is now before the U.S. Court of Appeals for the Fourth Circuit.

Although the outcome of the ACOG litigation is far from settled, the Biden administration could reverse course immediately and waive the enforcement of the in-person ETASU for the life of the pandemic and for the foreseeable future, just as the FDA has done for other drugs. Over the long term, a new FDA commissioner should begin the process of repealing the REMS applied to mifepristone.

Removing federal restrictions on medication abortion would foster the expansion of virtual clinics. Due to the district court's ruling this summer as well as the Gynuity investigational study, providers in 15 states and Washington, D.C., currently administer abortion via telemedicine (Baker, 2020). Virtual clinics and online pharmacies, many established in the last year, offer care that costs less, protects privacy, increases convenience, and reduces delay without compromising the efficacy or quality of care. Patients in places like Minnesota, where the state's handful of abortion clinics cluster in major cities, no longer have to drive hundreds of miles to pick up a safe and effective drug before driving back home to take it.

To be clear, measures like remote abortion have clear limitations; they depend on people having internet service or phones, for one. For another, they cannot serve people with high risk pregnancies — a population in which people of color are disproportionately represented (Harrison & Megibow, 2020). Finally, medication abortion cannot assist patients seeking terminations after 11 weeks of pregnancy.

That said, by lifting the nationwide FDA restriction, the new administration would encourage the growth of remote abortion services for the significant numbers of patient seeking to end early, uncomplicated pregnancies in the half the country that allows teleabortion.

Recommendations for Action

Federal government:

- The FDA should repeal or stop enforcing the REMS for medication abortion.
- Specifically, the FDA should issue guidance confirming the results of studies demonstrating medication abortion's safety and efficacy, allowing mifepristone to be ordered through mail-order prescription services and retrieved at retail pharmacies.
- The Biden administration should stop defending the lawsuit that seeks to lift a federal district court's injunction of the FDA in-person requirement.
- Congress should enact legislation that advances teleabortion by recognizing that medical abortion can be a health service appropriately included in plans for telemedicine's expansion.
- Congress should repeal the Hyde Amendment, which prohibits federal funding for almost all abortions.

State governments:

- Legislators should repeal an array of abortion regulations, such as waiting periods and in-person counseling, so that patients can avoid unnecessary visits to clinics and decrease the risk of COVID-19 exposure.
- Law enforcement and prosecutors abstain from applying criminal laws to punish self-managed abortion .
- Legislators should repeal restrictions on telemedicine as applied to abortion, such as in-person and physician-only administration of medication abortion.
- The legislature and state agencies, including state medical and licensure boards, should include medication abortion among the healthcare services subject to state efforts to expand telemedicine or to relax restrictions on telemedicine.
- State agencies should lift restrictions on telehealth modes (include audio-only communications), locations (use at home), delivery (health care providers operating across jurisdictions), and provider licensure (interstate licensure compacts).

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Access to Treatment for Individuals with Opioid Use Disorder

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SUMMARY. Highly effective medications to treat opioid use disorder (OUD) have existed for decades. Despite their proven efficacy, federal and state laws severely limit access to these medications, limitations that disproportionately impact those who are made particularly vulnerable by factors including economic injustice and structural racism. In response to the COVID-19 epidemic, the U.S. Drug Enforcement Administration (DEA) and other federal agencies have taken steps to temporarily remove some legal and regulatory barriers to these medications. Most of these changes are set to expire with the COVID-19 public health emergency declaration, although the epidemic of opioid-related harm will not end when the novel coronavirus is controlled. Indeed, data from many states show a sharp increase in opioid-related harm since the beginning of the COVID-19 pandemic. This Chapter highlights the positive impact of OUD treatment, recent changes to increase access to that treatment, and recommendations for permanently reducing legislative and regulatory barriers to effective, evidence-based interventions for OUD.

Introduction

Opioids, either alone or in combination with other substances, killed nearly 47,000 people in 2018, the latest year for which full data are available. Provisional data show that overdose-related deaths have accelerated since then, with more deaths recorded in the 12-month period ending May 2020 than in any other 12-month period on record. The number of Americans who use heroin more than doubled from 2002 to 2016, and an estimated two million Americans meet the criteria for opioid use disorder (OUD).

Laws at the federal, state, and local levels often act as structural barriers to evidence-based prevention and treatment, and in many cases perpetuate and amplify stigma-driven responses to people with OUD. This is particularly true for individuals made vulnerable by economic deprivation, structural racism, and other social determinants of health. Outside of the criminal justice system, which systematically harms and disenfranchises already vulnerable individuals, legal barriers to OUD treatment are the most poignant example of the negative impact of law on the health of people who use drugs (PWUD).

Medications for OUD have existed for decades. The most effective of these medications, methadone and buprenorphine, are referred to as opioid agonist treatment (OAT) because they activate or partially activate opioid receptors. These medications significantly reduce many of the potential harms associated with OUD, including relapse and bloodborne disease risk. Perhaps most importantly, treatment with either medication reduces both overdose-related and all-cause mortality risk in opioid-dependent individuals by approximately 50% (Sordo et al., 2017).

Because of their effectiveness and relative safety, the National Academies of Sciences, Engineering, and Medicine has declared that "[w]ithholding or failing to have available all classes of FDA-approved medication for the treatment of opioid use disorder in any care or criminal justice setting is denying appropriate medical treatment" (Leshner & Dzau, 2019). Alex Azar, the former secretary of Health and Human Services (HHS), has noted that attempting to treat OUD without OAT is "like trying to treat an infection without antibiotics" (Roubein, 2018).

Despite this rhetorical support from expert organizations and federal officials, unduly restrictive federal, state, and local laws and policies significantly impede access to OAT. While these legal and policy barriers are harmful in normal times, COVID-19 has compounded the risks to people with OUD, particularly for high-risk individuals. Preliminary CDC data show that more than 19,000 people died from a drug overdose in the first quarter of 2020, almost 3,000 more than the first quarter of 2019, and more than 40 states have reported an increase in opioid-related mortality as of December 2020.

This trend has been exacerbated by the COVID-19 crisis. The offices of many clinicians, treatment programs, and harm reduction services have had to close or significantly reduce their hours due to lockdowns and social distancing requirements, and disruptions to normal routines and increased social isolation increase the risk of returning to drug use for people in recovery. Many people who previously used drugs with other individuals who would be able to respond in an overdose emergency are now using alone, dramatically increasing the risk of fatal overdose.

Further, patients with OUD are at a significantly increased risk for COVID-19, and COVID-19 patients with OUD have significantly worse outcomes than those without OUD. This increased risk is especially pronounced in Black patients (Wang et al., 2020).

Legal Barriers to Opioid Agonist Treatment

Legal barriers to OAT are many and varied. Although methadone prescribed for pain is subject only to the restrictions that apply to all controlled substances, federal law imposes numerous additional limitations when it is used for OUD treatment. These restrictions begin with limits on which patients may receive the medication. To be considered for treatment, most individuals must have had OUD for at least one year and have received a full medical evaluation prior to receiving treatment. Federal law also limits the dosage that patients can receive, regardless of the prescriber's determination of their clinical need (Davis & Carr, 2019).

Moreover, while most drugs can be dispensed at any licensed pharmacy, only federally certified opioid treatment programs (OTP) may dispense methadone for OAT, and practitioners providing it must obtain an annual registration from the federal Drug Enforcement Agency (DEA). OTPs may provide methadone only in oral form, and patients generally must ingest it under the supervision of OTP staff. Although "take-home" doses are permissible, the terms under which patients are trusted with medication prescribed to them are set not by the prescriber but by federal law. Requirements for daily dosing disproportionately harm individuals without reliable transportation and make it nearly impossible for individuals who work non-standard shifts to access methadone treatment. For example, one study found that 20% of people in treatment reported difficulty getting to or from treatment as a reason for nonattendance, and another study found that 26% of patients traveled more than 15 miles to their OTP, and 6% traveled more than 50 miles (Network, 2020).

Several states, including many of those with a considerable population of people with OUD, have created additional barriers to accessing methadone for OAT. For example, Georgia limits each region of the state to a maximum of four licensed methadone programs, and West Virginia has a blanket moratorium on the establishment of new OTPs (Davis & Carr, 2019). Although several federal appellate courts have ruled that some laws that restrict the siting of OTPs violate the Americans with Disabilities Act, many states and localities implicitly or explicitly limit where they can be located — often pushing them far away from where most people live and into areas that are difficult to access via public transportation.

Federal restrictions on buprenorphine prescribed for OUD, while less severe than those imposed on methadone, also serve to ensure that some people who would benefit from the medication are left to suffer without (Davis & Carr, 2017). Perhaps the most important of these is that only health professionals who have received a federal "waiver" are permitted to prescribe buprenorphine for OUD. To qualify for a waiver, physicians must either hold a certification in addiction medicine or complete specific training, which usually includes an eight-hour series of instruction. Non-physicians must complete 24 hours of training. Federal law also limits the number of patients a waivered provider may treat.

These limitations conspire to artificially reduce the number of providers who offer buprenorphine, as well as the patients who can benefit from it. In 2016, nearly half of America's 3,100 counties, including more than 75% of rural counties, were without a single physician authorized to prescribe the medication (Andrilla et al., 2017). In fact, only 2% of waivered physicians practice in remote rural areas, even though as of 2018 the rate of non-medicinal use of opioids was greater in rural areas than urban areas, and the per capita overdose rate was nearly 45% higher in rural communities (Weintraub et al., 2018). Even when patients can access buprenorphine providers, they may have difficulty obtaining the medication from pharmacies. A recent survey of pharmacies in a rural area with high opioid overdose rates found that 80% limited buprenorphine dispensing, often because of concerns regarding potential violations of federal law (Cooper et al., 2020).

Similarly, the majority of methadone clinics are clustered in large urban centers, causing people in rural areas to have to drive large distances to access care. One study of the five states with the highest rates of opioid-related fatal overdose found that the average drive time to an OTP was 49 minutes for rural counties compared to approximately eight minutes in large central metro areas (Joudrey, P. J., et al., 2019).

Legal limitations on OAT also contribute to severe racial disparities in treatment access. Despite similar prevalence of OUD among Black and white adults, from 2012 to 2015 white patients were almost 35 times more likely to have a buprenorphine-related office visit compared to Black patients (Lagisetty et al., 2019). While patients should be free to choose which treatment they prefer, Black patients are often limited to methadone as their only option due to their location, despite an increase in opioid overdoses in Black communities (Nguemeni Tiako, M.J., 2020). In some programs, Black patients are subjected to tighter regulations including lower methadone dose limits and decreased likelihood of take-home doses.

Access to buprenorphine is also limited by the Ryan Haight Act, which permits controlled substances to be initially prescribed, in most instances, only after the prescriber has conducted an in-person examination of the potential patient. This requirement, which was designed to target illicit internet pharmacies, creates nearly insurmountable barriers for individuals who would benefit from buprenorphine treatment but are unable to meet with a waivered provider in person to begin therapy. Its effects fall particularly hard on individuals with OUD in rural areas, those without reliable transportation, and individuals with disabilities.

Although the DEA is charged with balancing the needs of ensuring access to controlled medications while limiting diversion, these restrictions all favor diversion control over medically indicated access. Diversion — that is, use of medications for OUD by someone other than the person to whom it was prescribed — is often raised as a justification for the limits imposed on OUD. However, studies evaluating the use of non-prescribed buprenorphine have demonstrated that it is primarily used for the purpose for which it was intended — helping people with OUD reduce use of other opioids and to treat symptoms of withdrawal (Chilcoat et

al., 2019). Indeed, among adults with OUD, greater frequency of non-prescribed buprenorphine use is significantly associated with lower risk of overdose (Carlson et al., 2020). Improving access to treatment would likely reduce this concern by reducing the demand for non-prescribed buprenorphine.

Changes during the COVID-19 Emergency

Federal agencies have temporarily removed some barriers to OAT during the COVID-19 pandemic. In the methadone context, the Substance Abuse and Mental Health Services Administration (SAMHSA) issued guidance in late March 2020 that allows states to permit all patients who are on a stable methadone dose to receive 28 days of take-home medication, and for patients who are less stable to receive 14 days of take-home medication (SAMHSA, 2020). It is up to states to request this ability, however, and individual programs to implement the change.

Further, in consultation with SAMHSA, DEA has temporarily permitted OTPs to provide patients who are otherwise permitted to receive take-home doses of methadone to obtain those doses from temporary off-site locations, provided they are in the same state in which the OTP is registered and meet certain other conditions. DEA also temporarily permits authorized OTP employees to personally deliver methadone to patients who cannot travel to the OTP to obtain the medication themselves and has authorized law enforcement and National Guard personnel to deliver methadone to patients as well. However, an individual must still present in-person to an OTP to begin methadone treatment.

In the buprenorphine context, the HHS secretary, in coordination with the attorney general, has used existing statutory authority to waive the Ryan Haight Act's in-person examination requirement, thereby permitting the initial consultation for buprenorphine treatment to be held via telemedicine. While this authority was initially limited to communication conducted via a real-time, two-way interactive audio-visual communication system, DEA used its enforcement discretion to authorize audio-only consultation as well. This innovation is key, as it permits "tele-bupe" services whereby an individual with OUD can quickly and easily contact a waivered physician who conducts a phone consultation and, where appropriate, prescribes buprenorphine and schedules appropriate follow-up. This is especially vital to the 21.3 million Americans who live in "digital deserts" and have no fixed broadband service, including almost half of low-income Americans and one-third of rural Americans (Khatri et al., 2020).

Further, the HHS Office for Civil Rights, which enforces the Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations, has issued a formal notice that it will "exercise its enforcement discretion and will not impose penalties for noncompliance with the regulatory requirements under the HIPAA Rules against covered health care providers in connection with the good faith provision of telehealth during the COVID-19 nationwide public health emergency," and that "[a] covered health care provider that wants to use audio or video communication technology to provide telehealth to patients during the COVID-19 nationwide public health emergency can use any non-public facing remote communication product that is available to communicate with patients" (HHS, 2020). While the office notes that many audio-visual tools are HIPAA compliant, this use of enforcement discretion will permit providers to interact with patients who may not have access to professional software, including via programs that are regularly used on cell phones.

In acknowledgement of the fact that some prescribers may be responding to the crisis outside of the state in which they normally practice, DEA has waived the requirement that a DEA-registered provider obtain a separate registration in each state in which they practice, if they are practicing in a state that has granted reciprocity to providers licensed in other states during the public health emergency. Since DEA considers a provider to be practicing in the state in which their patient is located, this change may further improve the ability of providers to prescribe buprenorphine via telemedicine, particularly in rural areas and in smaller states.

Implementation of these changes has been uneven. Many states impose their own restrictions on methadone for OAT, and modifications to those restrictions are necessary to fully implement the modifications to federal law. For example, New York has implemented delivery of methadone to high-risk patients who are more than 50 years old who are permitted at least seven days of take-home doses, and Oregon has issued guidance for OTPs that closely mirrors that from SAMHSA. Virginia's Medicaid program has provided guidance to OTPs that includes eliminating penalties for missed urine drug screens, and West Virginia has suspended counseling requirements for OTP patients during the COVID-19 emergency.

Federal flexibility regarding the use of telehealth seems to have been more widely implemented, likely due to the fact that telehealth for all fields of medicine has been expanded in the COVID-19 response. Many states have expanded their telehealth rules to include changes such as the approval of mental health providers' use of telehealth, payment parity with in-person visits, and authorized use of audio-only communication if necessary. However, some continue to impose limitations that exceed those in federal law.

Organizations in several states have begun offering buprenorphine hotlines, whereby individuals who want to begin buprenorphine treatment can connect with a waivered provider over the phone. The provider then conducts an intake with the patient, prescribes buprenorphine if medically indicated, and schedules follow-up appointments. These programs can greatly reduce barriers to care for individuals who live in rural areas or who otherwise have difficulty accessing a waivered provider. However, they are typically limited to individuals in certain geographical areas; there is no nationwide hotline to initiate buprenorphine treatment.

In December 2020, Congress passed the Coronavirus Response and Relief Supplemental Appropriations Act. Unfortunately, the Act did not contain any significant legal or regulatory changes regarding access to OAT. Early drafts included language that would have eliminated the buprenorphine waiver requirement, which would likely have greatly expanded the availability of OAT and helped to ameliorate the racial and socioeconomic disparities plaguing

access to OAT. However, the final text of the bill did not include this language. Instead, the law provides $4.25 billion for SAMHSA to provide increased mental health and substance abuse services and support, including $1.65 billion in funds for Substance Abuse and Prevention Treatment Block Grants, among other general mental health services funding.

Despite the changes made in response to the COVID-19 crisis, overdose deaths continue to rise. Further, all these legal changes are in effect only during the COVID-19 emergency, and many require action on the part of states and other agencies to fully implement. Once the pandemic is resolved and the new coronavirus-related emergency declarations have expired, the older restrictions are set to resume. Such an outcome would be contrary to common sense and evidence-based practice and should not be permitted to occur. Both federal and state governments should make these legislative and regulatory changes permanent to remove barriers to evidence-based OUD treatment. Congress should also act to remove barriers to OAT, such as the requirement that providers who prescribe buprenorphine for OAT receive a "waiver" before doing so, that have not been waived during the COVID-19 outbreak, to increase access to care.

Recommendations for Action

Federal government:

- To remove barriers to buprenorphine, Congress should remove or modify the waiver requirement and allow prescribing without an initial in-person evaluation.
  - Amend 21 U.S.C. § 829(e) to permit clinicians to prescribe buprenorphine for OUD treatment without an initial in-person evaluation, including through audio-only interactions where necessary, greatly increasing access to OAT to those in rural areas or without transportation;
  - Amend 21 U.S.C. § 823(g)(2) to permit all prescribers registered with the DEA to prescribe buprenorphine for OUD treatment without first obtaining a "waiver;"
  - Amend 21 U.S.C. § 823(g)(2)(B)(iii) to remove or increase the cap on the number of patients a waivered provider may treat with buprenorphine.
- To remove barriers to all opioid agonist medications, the Secretary of Health and Human Services (HHS), should permit treatment to be initiated via telehealth, remove restrictions on who can receive treatment, permit the prescribing physician to determine methadone dosing, and permit methadone to be dispensed outside of OTP.
  - In coordination with the Attorney General, use the statutory authority provided by 21 U.S.C. § 54(D) to waive the Ryan Haight Act's in-person examination requirement for the duration of the federally declared opioid emergency, greatly increasing access to OAT to those in rural areas or without transportation;
  - Remove restrictions on which patients may receive methadone for OUD by repealing 42 C.F.R. § 8.12(e);
  - Repeal the requirement in 42 C.F.R. § 8.12(f)(2) that a prospective OTP patient undergo a "complete, fully documented physical evaluation" before admission;
  - Repeal 42 C.F.R. § 8.12(h)(3)(ii) to remove initial dosing limitations on methadone treatment;
  - Modify 42 C.F.R. § 8.12(i) to liberalize limitations on take-home methadone dosing;
  - Modify 42 C.F.R. § 8.11(a)(1) to permit facilities such as pharmacies that do not meet all the requirements of 42 C.F.R. § 8.12 to dispense methadone for OUD treatment.
- The Attorney General should comply with the requirements of 21 U.S.C. § 831(h)(2) and promulgate regulations that permit all waivered clinicians to prescribe buprenorphine without conducting an in-person examination of the prospective patient.
- Federal agencies that provide funding to graduate medical education, particularly the Centers for Medicare

and Medicaid Services, should condition federal funding of residency programs on clinicians having received evidence-based instruction in OUD prevention, care, and treatment.

State governments:

- To remove barriers to opioid agonist treatment, legislators and regulatory agencies should remove restrictions on OTP siting, authorize provision of treatment via telehealth and implement a "hotline" for buprenorphine initiation, remove payment barriers to OAT, require newly licensed physicians to obtain a buprenorphine waiver, and require correctional facilities to offer OAT.
  - o Remove restrictions on OTP siting and forbid localities from imposing same;
  - o Authorize the provision of buprenorphine via telehealth where applicable;
  - o Remove prior authorization and other payment barriers to OAT;
  - o Ensure that state Medicaid programs cover methadone and buprenorphine as well as transportation to and from provider appointments;
  - o Require state and local correctional facilities to screen for OUD and offer OAT as appropriate;
  - o Require all newly licensed physicians to obtain a waiver to prescribe buprenorphine for OAT so long as the waiver requirement exists;
  - o Legislators should reform criminal and child protection laws that serve as barriers to treatment access;
  - o Regulatory agencies should enable individuals with OAT to access a waivered prescriber by calling a single, toll-free number.

Local governments:

- Local governments should remove legal and financial barriers to OTPs and other treatment programs.
  - o Modify zoning and licensing laws that create barriers to the establishment of and access to methadone treatment facilities;
  - o Fully fund prevention and treatment initiatives.

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Legal Strategies for Promoting Mental Health and Wellbeing in Relation to the COVID-19 Pandemic

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SUMMARY. The loss of life, severe illnesses, uncertainty, loneliness, and exhaustion related to COVID-19, together with the social and economic impacts of community mitigation measures, have taken a toll on mental health throughout the population. Many elderly, African-Americans, Latinos, Native Americans, Asian Americans, health care providers, public health professionals, essential workers, unemployed people, children, young adults, educators, parents, women, caregivers, LQBTQ people, prisoners, and people who live alone have experienced heightened stress, anxiety, depression, burnout, and isolation. Beyond treating individuals experiencing mental illness, law and policy can support mental health and wellbeing in four primary ways: (1) strengthen the social and economic safety net, (2) improve access to mental health care, (3) support mental health knowledge and skills, and (4) prevent self-harm and violence. Bolstering the ability to meet basic needs such as housing, food, childcare, and safer employment or unemployment benefits will reduce stress and improve health outcomes. Substantial, sustained investment in community mental health will expand access to treatment, increase use of public and private insurance, and overcome provider shortages, especially in rural communities and communities of color. Every educational setting must prioritize social and emotional wellbeing of students, educators, employees, and parents. Strengthening interventions including Psychological First Aid, the Crisis Counseling Program, suicide prevention, and violence prevention will support connectedness, nurture coping skills, and increase safety. Legal action to reverse structural racism and support mental health in communities of color is essential. Strategies to support posttraumatic growth should be at the forefront of pandemic response, recovery, and restructuring.

Introduction

The COVID-19 pandemic may be viewed as a mass trauma experienced throughout the United States and the rest of the world. Loss of life, severe illness, extended recovery periods, uncertainty, shortages of personal protective equipment, economic upheaval, limitations on daily activities, isolation, exhaustion, and structural racism have taken a substantial toll. By July 2020, more than 50% of respondents to a Kaiser Family Foundation Health Tracking Poll indicated that worry or stress about the new coronavirus had negatively affected their mental health (Hamel et al., 2020).

Scientific opinion has identified five key principles for response to mass trauma:

- Promote sense of safety
- Promote calming
- Promote sense of self- and collective efficacy
- Promote connectedness
- Promote hope

(Hobfoll et al., 2007). These principles provide valuable guidance for assessing and strengthening the legal response to the COVID-19 pandemic. A backlash against community mitigation measures and growing disinformation and skepticism about the very nature of the pandemic undermined each of these principles.

COVID-19 has been characterized by disparities in infection and mortality rates for communities of color, based in part upon disproportionate representation in low-wage service jobs at high risk for COVID-19, greater exposure to adverse environmental factors such as air pollution and limited access to nutritious food, as well as higher rates of chronic disease such as diabetes, asthma, and cardiovascular disease. These disparities have resulted in a

greater burden of grief for many people of color and increased anxiety for those worried about the high levels of risk to themselves and their communities (Purtle et al., 2020). These effects were compounded by concurrent racial trauma, with the death of George Floyd at the hands of Minneapolis police. The Hogg Foundation in Texas has urged adoption of declarations of racism as a mental health issue (Hogg Foundation, 2020). Evidence-based legal strategies to address structural racism and strengthen protective factors are necessary to increase health equity.

The field of positive psychology posits a "dual continuum" model, which considers both mental illness and mental health (also referred to as flourishing). According to the research, people who are flourishing typically engage in six daily activities: interacting, helping others, playing, moving (physical activity), spiritual activity, and learning something new (Catalino & Fredrickson, 2011). The COVID-19 pandemic and community mitigation measures disrupted daily routines and combined to threaten these core pillars of wellbeing on a greater scale than most people have previously experienced in their lifetimes. To withstand the remainder of the pandemic, as well as improve our capacity to flourish as individuals and as a society in the face of future challenges, including pandemics, we must (1) strengthen the social and economic safety net, (2) improve access to mental health care, (3) support mental health knowledge and skills, and (4) prevent self-harm and violence.

Strengthen the Social and Economic Safety Net

Federal legislation enacted in response to the COVID-19 pandemic sought to address the conditions that might otherwise have contributed to even poorer mental health (Purtle et al., 2020). This assistance and associated recommendations are discussed in other Chapters of this Report and include unemployment benefits; moratoria on evictions; SNAP and a modified National School Lunch Program; paid sick leave for those remaining at home while ill with the new coronavirus; and paid family leave for those caring for those ill with the new coronavirus, or for children home from school. Because many of these legal interventions were time-limited, however, recipients experienced anxiety and uncertainty about when and whether Congress would extend or terminate these social supports.

Improve Access to Mental Health Care

Among the general population affected by the pandemic, some needed only short-term mental health care. One means of providing emergency mental health care is through the Crisis Counseling Program (CCP) authorized under the Stafford Act when there is a major disaster declaration, but not when there is an emergency declaration. Through the CCP, the federal government provides federal funding and technical assistance to states, territories, and Tribes. The CCP provides support with problem-solving and coping skills, thus enhancing self-efficacy. The president approved major disaster declarations for all 50 states, the District of Columbia, and four territories due to the pandemic in 2020. Stafford Act provisions limiting the CCP to nine months following a major disaster declaration should be amended to make the CCP available for a longer time during ongoing declared emergencies, including public health emergencies.

The Mental Health Parity and Addiction Equity Act of 2008 and the Affordable Care Act provide that to the extent private health insurers provide insurance coverage for physical health concerns, their coverage for mental health concerns must be comparable. However, these laws have not resulted in parity in coverage for mental health treatment, due to lack of enforcement among other problems. This requirement also applies to public insurance, but the federal and state governments have not maximized use of Early Periodic Screening, Diagnosis and Treatment under Medicaid to provide mental health promotion and treatment services to children at highest risk, including during the pandemic (Counts et al., 2020). One bright spot with respect to individual mental health treatment during the pandemic was administrative changes by the Centers for Medicare and Medicaid Services (CMS) and the Office of Civil Rights (OCR) within the Department of Health and Human Services to expand eligibility for reimbursement for telehealth and to suspend requirements related to privacy and security of platforms for telehealth. CMS and OCR should consider strategies to expand access to telehealth permanently, as discussed further in Chapter 16, "Telehealth and Inequity during the COVID-19 Response."

Support Mental Health Knowledge and Skills

The pandemic has highlighted critical gaps in mental health literacy and skills, as well as opportunities to strengthen social and emotional learning and skill development. This knowledge and skillset is essential throughout the population, and particularly among children, parents, educators, health care providers, and first responders.

Investments in home visiting programs, parenting skills programs, and universal pre-kindergarten are all strategies that can prevent adverse childhood experiences, nurture coping skills, and promote emotional wellbeing and connectedness. The federal Every Student Succeeds Act provides grants to state and local education agencies to create the conditions for student learning and improve the school climate. Before the pandemic, ratios of school counselors and mental health professionals to students were inadequate. The need will be greater post-pandemic. The mental health of all people within school, university, and community college systems — from teachers and school employees, to students and parents — warrants sustained legal and policy attention. State laws, learning standards, and benchmarks may advance social and emotional learning. These educational approaches can be implemented in-person and online (CASEL, 2020). Other state laws may promote school mental health in the context of the COVID-19 pandemic — examples include a law requiring instruction in mental health first aid for teachers in Florida; laws requiring that mental health be addressed in health education courses in New York and Virginia; and an Oregon law recognizing student absences for mental health. A growing body of evidence supports the importance of access to nature for mental health, such that the Great American Outdoors Act may provide opportunities to reduce stress and increase equity.

As the pandemic enters a second year in the United States, exhaustion and burnout are substantial concerns among health care providers and first responders (Shechter, 2020). Prior

investments in emergency preparedness research resulted in online curriculum and trainings in Psychological First Aid, and policy adoption among health departments and health care systems (Birkhead & Vermeulen, 2018). The Pandemic and All Hazards Preparedness and Advancing Innovation Act of 2019 authorizes the hospital preparedness program, which provides funds and technical assistance for health care coalitions to engage in efforts to encourage a resilient health care workforce, which may include training in psychological first aid. The Coronavirus Aid, Relief, and Economic Security (CARES) Act included additional funding for hospital preparedness. The Coronavirus Response and Relief Supplemental Appropriations Act of 2021, passed in December 2020 as Division M of the Consolidated Appropriations Act of 2021 (CRRSA Act), dwarfs the investment in mental health of any prior COVID-relief bill, with $4.25 billion. This renewed investment in research and training is needed, including in culturally competent approaches to support purpose and resilience in the health care workforce and their patients.

The CRRSA Act allocated more funding for mental health by orders of magnitude, though most of it seems destined for mental health treatment. Future legislation should prioritize mental health promotion, commensurate with the detrimental impact of COVID-19 on mental health throughout the population. As the experience of elderly residents of nursing homes demonstrates, promoting social connections to combat loneliness should be as much a priority as infectious disease control measures. In order to inspire hope, as it begins to focus on a longer-term vision for recovery, Congress should search for models that support posttraumatic growth among populations, such as interventions with veterans.

Prevent Self-Harm and Violence

Until social and emotional skills in self-awareness and self-management are universally taught and embraced, crises like the pandemic are likely to raise concerns about potential increases in suicide, child abuse, domestic violence, and substance use disorder. Suicide rates were at historic highs prior to the COVID-19 pandemic. They may increase substantially, based upon reported suicidal ideation, especially among young people in summer 2020 (Czeisler et al., 2020). The CARES Act and the CRRSA Act of 2021 each authorized $50 million for suicide prevention. Evidence-based laws that decrease the risk of suicide include the Garrett Lee Smith Act, which provides for grants from the federal government to state and Tribal communities as well as colleges for training gatekeepers, those who are in regular contact with young people but are not mental health professionals, in basic suicide prevention. Other effective legal interventions include lethal means control, including lethal means education, safe storage initiatives, and extreme risk protection orders for those shown to be a danger to themselves or others. Implementing continuing education requirements at the state level regarding suicide prevention and mental health for health care providers may also improve suicide prevention, especially for individuals who may not fall into an identified higher risk group. Programs to enhance social and emotional learning and skill development and encourage social connections, such as those described above, are also strategies to prevent violence.

Recommendations for Action

Federal government:

- Congress should strengthen the safety net to more robustly address the economic disruptions and practical needs created by the pandemic, as set forth in the relevant Chapters.
- Congress and HHS should expand access to mental health care and treatment, especially for those most affected by the health consequences of the pandemic and the economic consequences of community mitigation measures, and those most at risk of being adversely affected:
  - Enforce mental health parity requirements;
  - Extend changes to telehealth regulations and consider making them permanent;
  - Work with states to maximize utilization of Medicaid funds, including EPSDT for children;
  - Increase funding to training and recruitment programs to address mental health provider shortages and increase the proportion of culturally competent providers.
- Congress, HHS, the Department of Education, and the Department of the Interior should increase their commitment to mental health promotion, including providing opportunities to build knowledge and skills related to mental health and wellbeing:
  - Increase investment in maternal, infant, and early childhood home visiting programs;
  - Create the conditions for student learning, including social and emotional learning, trauma-informed education, and Mental Health First Aid;
  - Link receipt of emergency preparedness funds for hospitals and healthcare coalitions to ongoing, culturally competent training in Psychological First Aid, Skills for Psychological Recovery, and preventing and addressing burnout among front-line healthcare and mental health providers;
  - Prioritize states and communities hardest hit by morbidity, mortality, and economic impacts of COVID-19 for funding under the Great American Outdoors Act.
- Congress and SAMHSA should use suicide prevention funds to serve identified high-risk populations and the general population.
  - Increase funding for Gatekeeper training for suicide prevention among youth and young adults, especially those who are Native American, African-American, people of color, LGBTQ, and live in rural communities, through the Garrett Lee Smith Act.

State governments:

- State governors, agencies, and legislatures should strengthen the safety net to more robustly address the economic disruptions and practical needs exacerbated by the pandemic, as set forth in the relevant Chapters.
- State governors, agencies, and legislatures should expand access to mental health care and treatment, especially for those most affected by the health consequences of the pandemic and the economic consequences of community mitigation measures, and those most at risk of being adversely affected:
  - Enforce mental health parity requirements;
  - Work with CMS to maximize utilization of Medicaid funds, including EPSDT for children, to promote mental health and treat mental illness;
  - Extend changes to telehealth regulations and consider making them permanent;
  - Join the Psychology Interjurisdictional Compact to overcome licensure limitations to expand tele-mental health;
  - Provide a pathway for psychologists to gain prescribing authority.
- State governors, agencies, and legislatures should increase their commitment to mental health promotion, including providing opportunities to build knowledge and skills related to mental health and wellbeing:
  - Issue a declaration of racism as a mental health crisis, or add mental health to a declaration of racism as a public health crisis, and implement measures to address declaration;
  - Increase investment in maternal, infant, and early childhood home visiting programs;
  - Make free, public pre-kindergarten

available to all children in the state, or to all children whose parents or caregivers are eligible for WIC;

- Provide flexible yet robust benchmarks, funding, and technical assistance to local educational agencies to create the conditions for student learning, including social and emotional learning, trauma-informed education, and Mental Health First Aid;
- Fund mental health education and services in public universities and community colleges;
- Enact and implement laws to promote safe storage of firearms and limit access to guns among those who are shown to pose a danger to themselves or others (extreme risk protection orders);
- Support ongoing, culturally competent training in Psychological First Aid, Skills for Psychological Recovery, and preventing and addressing burnout among front-line healthcare and mental health providers;
- When determining allocation of state and federal funds to acquire, expand, or maintain green space, prioritize communities hardest hit by morbidity, mortality, and economic impacts of COVID-19;
- In community mitigation executive orders and statutes, prioritize keeping institutions which contribute most to flourishing and economic stability, such as schools, open to the extent this may be done safely.

- State governors, agencies, and legislators should prioritize suicide prevention:
  - Implement gatekeeper training for suicide prevention among youth and young adults, especially those who are Native American, African-American, people of color, LGBTQ, and live in rural communities;
  - Incorporate mental health assessment and suicide prevention in continuing education requirements for health care providers, including mental health providers.

Local governments:

- Local health officers, boards of health, school boards, and elected officials should increase their commitment to mental health promotion, including providing opportunities to build knowledge and skills related to mental health and wellbeing:
  - Issue a declaration of racism as a mental health crisis, or add mental health to a declaration of racism as a public health crisis and implement measures to address declaration;
  - Prioritize those at greatest risk for adverse impacts of the pandemic for maternal, infant, and early childhood home visiting programs;
  - Make free, public pre-kindergarten available to all children in the jurisdiction, or to all children whose parents or caregivers are eligible for WIC;
  - Establish and implement polices to create the conditions for student learning, including social and emotional learning, trauma-informed education, and Mental Health First Aid;
  - Support ongoing, culturally competent training in Psychological First Aid, Skills for Psychological Recovery, and preventing and addressing burnout among public health professionals;
  - When determining allocation of state and federal funds to acquire, expand, or maintain green space, prioritize communities and neighborhoods hardest hit by morbidity, mortality, and economic impacts of COVID-19.
- Local governments should:
  - Prioritize keeping institutions which contribute most to flourishing and economic stability, such as schools, open to the extent this may be done safely when operating under community mitigation ordinances and orders;
  - Develop and expand systems to respond to mental and behavioral health emergencies with mental and behavioral health providers rather than law enforcement.

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Implementation and Enforcement of Quality and Safety in Long-Term Care

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SUMMARY. To understand how long-term care facilities, which less than 1% of the U.S. population lives in, became the source of more than 35% of COVID-19 deaths, you have to look beyond the vulnerability of the residents and examine how these facilities manage their employees and are regulated. Throughout the pandemic, grim reports consistently identified inadequate staffing, lack of effective infectious disease control and prevention, and poor emergency planning, as all factors that contributed to the death toll among residents and workers. In an effort to curb infection rates, federal emergency laws were passed, including the first universal paid sick leave law, and billions of federal government dollars were distributed to these facilities. In addition, the CDC Advisory Committee on Immunization Practices recommended targeting the limited vaccine doses to long-term care facilities first, in Phase 1a, which most states followed. However, these federal efforts failed to reach many of the intended constituents due to inequities around race, age, gender, socio-economic, and citizenship status. This Chapter provides recommendations on how to improve upon implementation of these federal efforts so that they are optimally and universally applied for a more resilient and equitable long-term care system.

Introduction

As the pandemic spread across the country, long-term care facilities struggled to prevent and contain outbreaks. While some challenges receded with greater precautions and better coordination between levels of government, a growing political and public outcry of dissatisfaction continues around quality of care and safety oversight. These issues were discussed in Chapter 19 in *Assessing Legal Responses to COVID-19: Volume I*.

The Chapter in Volume I highlighted three major missteps around staffing, infectious disease control and prevention, and emergency planning, then recommended strengthened legislation with regulatory oversight and enforcement. This Chapter provides an update on these missteps and offers a detailed analysis of how some of the laws that were passed with the specific intent to curtail COVID-19 infection rates were not universally implemented due to long-standing inequities. This Chapter concludes with recommendations to adopt at the federal, state, and local levels to address these inequities and improve long-term care going forward.

Updates

Staffing

There are approximately 1.2 million direct care workers in long-term care; these include nurses, certified nursing assistants, and personal care aides (Denny-Brown, et al., 2020). These workers are predominantly recent immigrants, women of color, and women with little education who earn low wages, with the average worker earning less than $30,000 annually. In order to earn enough of an income to support themselves and their families, many of these workers are employed at multiple long-term care facilities and in-home health care (Milczarek-Desai & Sklar, 2021).

When COVID-19 started to spread throughout the country, the combination of working in different long-term care settings and the inability to take paid sick leave led to alarming consequences. Specifically, nearly half of COVID-19 infections in long-term care facilities have been traced to staff who work in multiple facilities and who engage in "presenteeism," meaning they continue to work even after being exposed to or falling ill from COVID-19 (Chen et al., 2020). Presenteeism occurred despite the federal Families First Coronavirus Response Act (FFCRA), which required 14 days of paid sick leave for COVID-19 related reasons. This troubling finding highlights how essential it is for long-term care reform efforts to begin with better support for direct care workers, including mandating adequate staff-to-resident ratios, higher wages, and access to benefits, including paid sick leave.

Throughout the pandemic, direct care workers voiced complaints of unsafe working conditions and pressure to work while unwell, which were largely ignored. The refusal by legislators, regulators,

and industry leaders to address these concerns may have contributed to negative consequences in curtailing the spread of COVID-19, leading to extensive vaccine hesitancy among direct care workers and widespread staff vacancies in long-term care facilities.

In regard to access to vaccines, as many as half of direct care workers report vaccine hesitancy across the country. Recruiting and retaining direct care workers was difficult prior to the pandemic, and this need is expected to grow with an increasingly older population. While there is a federal law that requires minimum staffing levels, the Nursing Home Reform Law of 1987, and 41 states have passed higher staffing standards than this federal law, experts claim the ratios still fail to adequately protect older residents (Harrington et al., 2016). COVID-19 has also contributed to the growing need for well-trained staff given the high rates of delirium, cognitive dysfunction, and neurological damage being reported among older, COVID-19 survivors (Liotta, et al., 2020). Treatment for these ailments requires regular human interaction and rehabilitation, which mean time-intensive efforts by direct care workers, in order for these survivors to recover as completely as possible.

In order for federal and state efforts, such as paid sick leave legislation and vaccine distribution to effectively reach these intended direct worker constituents, these efforts must be bolstered by a long-term care system that workers can trust and feel a sense of safety.

Infectious disease control and prevention

Complaints from direct care workers in long-term care regarding workplace safety were largely dismissed by the Occupational Safety and Health Administration (OSHA), which did not execute legally binding regulations and failed to investigate the vast majority of complaints. There are current federal regulations to protect employees from hazardous conditions under the General Duty Clause, which during the pandemic could authorize the use of PPE. Under this clause, OSHA could have issued a directive requiring employers to comply with CDC guidelines for PPE and other safety measures, but it did not do so. Furthermore, OSHA's enforcement was minimal, with only a handful of onsite inspections conducted in response to thousands of complaints from direct care workers.

As the death toll rose over this past year in long-term care settings, so followed a great deal of industry resources focused on pushing through legal immunity to nursing homes. At present, COVID-19 legal immunity or shields have passed in over half the states. A central argument of industry groups requesting immunity is the national shortage around PPE and testing kits that limits their ability to control the spread of COVID-19 in facilities. However, even as PPE, testing, and now vaccines have become more widely available, this new immunity shield may continue longer than intended and hide misconduct unrelated to COVID-19. Furthermore, the pandemic has resulted in a substantial reduction in onsite inspections from regulators, which makes this immunity all the more concerning for ensuring minimum standards of care (Sklar & Terry, 2020).

Data and enforcement

The U.S. Department of Health and Human Services, Office of Inspector General (OIG) conducted a study to assess the sufficiency of Centers for Medicare and Medicaid Services (CMS) oversight of skilled nursing facilities (SNF) or nursing homes, which include approximately 15,500 facilities that have been certified by Medicare as 'skilled' (Grimm, 2020). There are an additional 28,000 assisted living centers that are also considered long-term care facilities, but they mainly provide custodial care beds and do not receive the same level of regulatory oversight and reimbursement from CMS.

OIG examined the number of infection control and complaint onsite surveys conducted from March 23 to May 30, 2020 at SNFs. This report found a decrease in overall inspections and wide variation among the states. Specifically, there was a 22% drop in SNFs receiving an onsite survey, and some states, including Arizona, reported that no surveys were conducted onsite at any nursing homes. Also, very few deficiencies were found nationwide suggesting that even the onsite inspections that were conducted may not have been thorough.

OIG concludes its report by recommending for CMS to work with SNFs to overcome PPE and staffing challenges. Facilities that receive CMS funding must comply with Conditions of Participation, which establish standards for quality of care metrics, including staffing, which CMS monitors and rates on a five-star system (Conditions of Participation, 2020). In theory, such monitoring should lead to data-driven regulation, where poorly performing facilities could be identified and improved.

Additionally, more comprehensive data could lead to more targeted federal and state funding efforts. For example, in May 2020, HHS distributed $4.9 billion to SNFs based solely on the number of beds, and did not include variables, such as PPE and staffing shortages. In August 2020, another $5 billion was announced for distribution. This HHS package included an incentive-based program with performance metrics to reward SNFs that have maintained a safe environment, but it is unclear whether this latest round of funds improved the level of care for higher risk SNFs that may have overall lower performance outcomes.

By contrast, The Quality Care for Nursing Home Residents and Workers During Covid-19 Act that was introduced on May 5, 2020, (Quality Care for Nursing Home Residents, 2020) specifically proposes to increase regulatory inspections with stricter protocols and distribution of funds tied to improving the level of care. Ultimately, more funding alone or only rewarding high performers may have a limited impact compared to linking dollars where they can be of the most use to improve quality and safety.

Lastly, there continues to be calls for better data: timely, accurate, reliable, and including race demographics about COVID-19 cases across long-term care settings. CMS released an interim final rule in May 2020 that required SNFs to submit weekly updates to CMS and CDC about confirmed and suspected COVID-19 infections and deaths at their facilities, PPE supplies, and staffing shortages (85 Fed. Reg. 27550, 2020). The rule did not include a requirement to

report demographic data related to COVID-19 cases and deaths, and there is currently no published data on the race of SNFs residents and workers by facility (Gebeloff et al., 2020).

Emergency planning and accountability

One of the more concerning missteps was when some governors issued executive orders to transfer recovering COVID-19 patients to long-term care facilities in order to free up intensive care unit beds. However, some of these facilities lacked sufficient PPE, testing kits, adequate staffing, and ability to isolate residents, which likely contributed to subsequent outbreaks.

For example, Governor Cuomo issued this controversial order in New York on March 25, 2020, then reversed it on May 10, 2020, claiming the long-term care facilities should not have admitted these patients if they couldn't isolate them. However, this runs counter to the order which states, "no resident shall be denied re-admission or admission to the [long-term care facility] solely based on confirmed or suspected COVID-19" (Graham, 2020). If a resident was not critically ill, it was unclear how a facility could deny admissions. Clearly, a more coordinated effort between the different levels of government and health care settings is essential to protect the public and minimize harm during a public health emergency.

Addressing Inequities in Implementation of Paid Sick Leave Laws

The prior Sections describe the treatment of direct care workers in long-term care, which highlight the racial, gender, and economic inequalities they experience, despite their essential role in caring for older Americans. This Section examines why so many direct care workers were unable to access paid sick leave during the pandemic even with federal, state, and local legislation requiring paid sick leave.

When female workers became ill with COVID-19 many did not take sick leave. First, many simply did not know they had a right to paid sick leave under the FFCRA. Second, they may not have been eligible because of their status as independent contractors rather than employees. Third, many may have failed to request sick leave for fear of retaliation, including loss of employment. Lastly, many feared their employer might expose them or co-habiting family members to deportation.

While the FFCRA is a milestone, there are more than 40 paid sick leave laws in cities, counties, and states nationwide. Even if FFCRA didn't apply to a direct care worker because of their employment status as an independent contractor, some of these other paid sick leave laws may have applied because they are based solely on hours worked. It is essential to understand how paid sick leave laws can be made more accessible to the constituents, such as direct care workers, that they are most intended to support.

How to Make Paid Sick Leave Work as Intended

First, these laws need to be enforced. Nearly all paid sick leave law violations require federal or state labor agency intervention. These agencies, however, often lack adequate resources to investigate and hold employers accountable should they retaliate against workers.

Second, most of these agencies are highly centralized and are unlikely to conduct effective outreach to immigrant communities, so both employers and employees are often unaware of paid sick leave laws. Some pioneering examples of state and local governments reducing barriers include posting guidance online in multiple languages about paid sick leave and conducting tele-town halls to help workers and employers understand their respective paid sick time rights and obligations.

Recommendations for Action

As of February 2021, there have been more than 160,000 COVID-19 deaths from long-term care residents and staff. Their exposure to COVID-19 largely occurred due to staff working in multiple facilities when they were unwell and many of these same workers are now experiencing vaccine hesitancy. These recommendations attempt to mitigate the continued spread of COVID-19 as well as support a long-term care system that is incentivized by laws and regulations to prioritize the health and safety of residents and staff.

An urgent direct step that can be taken immediately to help reduce COVID-19 exposure in long-term care facilities is to extend paid sick leave legislation at the federal and state levels, and also include local community outreach and enforcement. If this legislation could be tied to paid leave for recovery from the COVID-19 vaccines, then that may also help reduce vaccine hesitancy.

Federal government:

- Congress should pass an updated Nursing Home Reform Law that aligns with experts' recommendations for adequate staff-to-resident ratios.
- Congress should consider the proposed Quality Care for Nursing Home Residents and Workers During COVID-19 Act of 2020 in the next coronavirus relief package or similar legislation to better link funding with quality and safety, including minimum staffing levels and paid sick leave based on hours worked.
- CMS should expand the metrics it collects on nursing homes to include race demographic data.

State governments:

- State legislators should pass or amend legislation that requires minimum staffing levels at all long-term care facilities to align with expert recommendations.
- States should pass or amend paid sick leave laws to ensure there is funding for conducting outreach to immigrant communities and other vulnerable population groups, funding for enforcement, and retaliation protection.
- States should pass legislation that requires all licensed long-term care providers to provide a minimum wage to direct care workers that align with expert recommendations.

Local governments:

- Cities and counties should pass or amend paid sick leave laws to ensure there is funding for conducting outreach to immigrant communities and other vulnerable population groups, funding for enforcement, and retaliation protection.

About the Author

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PART 4

Assuring Access to Medicines and Medical Supplies

Strategies to Address the Chronic Shortage of N95 Masks and Other Filtering Facepiece Respirators during the COVID-19 Pandemic

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SUMMARY. In March 2020, healthcare workers sounded the alarm on social media: #GetMePPE. As shortages of personal protective equipment (PPE) coincided with surges in hospital emergency department and intensive care unit capacity due to COVID-19, it became clear that a coordinated national strategy for PPE was needed. The Food and Drug Administration (FDA) released a series of guidance documents, accompanied by permissive emergency use authorizations (EUAs), to address the manufacture and use of PPE in health care settings. This article reviews actions taken by the FDA in response to the PPE shortage and the progress made in 2020 on procuring PPE for health care facilities. Given that N95 masks provide an essential barrier against droplet and aerosol transmission of SARS-CoV-2, this Chapter focuses on shortages of filtering facepiece respirators (FFRs). Finally, the Chapter offers solutions for federal and state policymakers, including the Biden administration, for the COVID-19 pandemic and beyond.

Introduction

In the United States, the COVID-19 pandemic unmasked a fragmented and under-resourced public health system that failed to quell a lethal respiratory illness from rampant spread. As support for public health agencies has dwindled over the last few decades, so did preparedness for infectious disease epidemics. President Trump's decision to disband the National Security Council's pandemic office in 2018 is just one recent example. In fact, several government reports in the last 15 years highlighted the need for more and better PPE during outbreaks of emerging infectious diseases, calling for greater research and investment; those recommendations were largely ignored by federal authorities (Sinha et al., 2020).

In spite of these warnings, the United States has become increasingly reliant on foreign production of PPE, greatly limiting its ability to scale up domestic manufacturing during emergencies. A year into the COVID-19 pandemic, the situation has substantially worsened domestically, and PPE shortages persist. A recent study identified four major contributing factors to PPE shortages: (1) limited reserves in hospitals; (2) surge demand that could not match supply; (3) failure to adequately maintain the national stockpile; and (4) dependence on foreign manufacturing that is highly susceptible to supply chain disruptions (Cohen & Rodgers, 2020). In fact, more than 70% of medical grade face masks used in the United States were imported from China in 2019; China's decision to nationalize its PPE supply in February 2020 caused significant disruption to PPE supplies in the United States (Congressional Research Service, 2020a). For more information on PPE and COVID-19, please see Chapter 20 in *Assessing Legal Responses to COVID-19: Volume I*.

Federal Laws and Regulations Governing PPE

FDA Regulation and NIOSH Certification of Medical Devices

Most medical grade PPE is regulated by the FDA as a medical device, pursuant to authority under the Federal Food, Drug, and Cosmetic Act. Oversight of medical devices is less rigorous than that of pharmaceuticals, requiring only a demonstration of substantial equivalence — comparable safety and efficacy — to one or more marketed devices. A 510(k) premarket notification, coupled with agency finding of substantial equivalence, clears the device for marketing and commercial distribution. For certain respiratory devices like filtering facepiece respirators (FFRs) and powered air purifying respirators (PAPRs), the National Institute of Occupational Safety and Health (NIOSH) must test and certify the product prior to filing a 510(k) premarket notification with the FDA.

OSHA Regulation of Workplace Safety

The Occupational Safety and Health Administration (OSHA) regulates the safety and health of workplaces, including health care facilities. This includes the authority to require respiratory

protection programs and use of protective equipment approved by NIOSH, as well as to issue permanent and temporary standards that regulate exposures, including new sources of harm such as COVID-19 (Congressional Research Service, 2020b). OSHA has yet to issue new requirements for occupational COVID-19 exposure, but did issue an Updated Interim Enforcement Response Plan for COVID-19 in May (OSHA, 2020). On January 22, 2021, President Joe Biden issued an executive order directing OSHA to issue revised guidance on workplace safety within two weeks, with new emergency temporary standards, if necessary, by March 15, 2021.

Twenty-eight state workplace safety and health plans have been approved by OSHA under Section 18(b) of the OSH Act. State plans, which must be as protective as federal OSHA standards, give state officials full authority to regulate workplace safety within their borders, but OSHA can rescind the approval at any time. At least eight states (California, North Carolina, Michigan, Minnesota, Oregon, Utah, Virginia, and Washington) have unique PPE standards.

PPE and the COVID-19 Pandemic

Emergency Regulation of PPE

In his early February 2020 declaration of a public health emergency, Secretary of Health and Human Services (HHS) Alex Azar declared that the circumstances warranted emergency use of in vitro diagnostics and other medical devices for responding to COVID-19. Since that time, the FDA has issued several emergency use authorizations (EUAs) that allow non-FDA approved medical products to be used for the COVID-19 response — in the absence of adequate FDA-approved alternatives (U.S. Food and Drug Administration, 2020b). EUAs expire upon resolution of the public health emergency, as determined by the Secretary of HHS. The public health emergency and the EUAs are issued on a temporary basis, requiring routine reassessment and renewal if warranted. The FDA has also issued and frequently updated guidance documents for manufacturers seeking to produce novel medical devices for responding to COVID-19 PPE shortages. NIOSH guidance during COVID-19 included strategies for optimizing supply of PPE: extended use, reuse, and decontamination and use of N95s beyond their shelf-life (NIOSH, 2020). When continually renewed, the EUA process may not incentivize manufacturers to pursue full approval for their products, and may complicate post-market surveillance.

Sourcing of PPE

The federal government has multiple levers by which it can compel production, acquisition, and distribution of PPE. The Defense Production Act (DPA) allows the president to commandeer the manufacturing of essential products during national emergencies (discussed in Chapter 24). The Trump administration declined to invoke the full authority of DPA, instead opting to enter into a variety of lucrative private contracts with entities that often had little or no prior experience in PPE manufacture or procurement. Many were unable to fulfill the obligations of those contracts; fraud and other criminal activity occurred as well. The Department of Justice has commenced 33 criminal and 11 civil cases involving COVID-19 related fraud, and U.S. Attorney General William Barr established the COVID-19 Hoarding and Price Gouging Task Force to address illegal activity related to PPE (Congressional Research Service, 2020a).

The Office of the Assistant Secretary for Preparedness and Response (ASPR, within HHS), worked closely with the Federal Emergency Management Agency (FEMA) on acquisition and distribution of PPE from the Strategic National Stockpile (SNS). During the COVID-19 pandemic, the stockpile has often been unable to accommodate state needs for PPE and other critical medical supplies. The latest COVID-19 relief, part of the 2021 omnibus, allocates $22.4 billion to the "Public Health and Social Services Emergency Fund," which may be used to cover PPE. The law also requires a report "containing a whole-of-government plan for an effective response to subsequent major outbreaks of the COVID-19 pandemic and for other future global pandemic diseases," which must include a section on PPE procurement and distribution (Title VI, Sec. 621(B)(2)(G)). In December 2020, the Congressional Research Service also made several recommendations for the new administration to consider in ensuring sufficient emergency PPE supply (Congressional Research Service, 2020a). The report recommends replenishing the SNS, expanding domestic manufacturing, supply chain control and distribution, and encouraging the use of the DPA. President Biden is already following these recommendations: in one of his first executive orders, he directed federal agencies to use the DPA to ramp up PPE production, though specifics are lacking.

Filtering Facepiece Respirators

FFRs like N95 masks (**N**ot resistant to oil, **95**% filter efficiency) are a critical component of infection control against contagious respiratory illnesses like COVID-19. N95 masks have three primary properties: (1) the ability to filter out small particles; (2) low inhalation resistance so that a user's oxygen supply is not limited; and (3) a tight fit to the face so that inhaled and exhaled air is directed through the filter. Qualitative fit is evaluated through a process known as fit testing, which is routinely conducted in health care settings and ensures that the mask forms a tight seal with the user's face. Quantitative testing evaluates filtration efficiency, confirming that the material filters particles effectively without posing harm to the user. Health care institutions are rarely able to measure filtration efficiency.

Shortages of masks, gloves, gowns, shields, and other PPE have resulted in health care-acquired infections and deaths. In a study of frontline health care workers in the United States and United Kingdom between March 24, 2020, and April 23, 2020, health care workers of color were more likely to be caring for patients with COVID-19, more likely to report inadequate or reused PPE, and nearly twice as likely as white colleagues to test positive for COVID-19 — five times more likely than the general public (Nguyen et al., 2020). Inadequate PPE correlated with a 30% greater chance of infection as compared to health care workers with adequate supplies.

Imported and counterfeit face masks. In addition to facilitating the manufacture of alternative PPE, the FDA issued EUAs in March

2020 permitting the importation and use of non-NIOSH approved masks that have met functionally equivalent international standards. N95 masks sold in the United States are regulated by the FDA and tested to standards set by NIOSH. Similar foreign standards and enforcement mechanisms exist, including in China (KN95, meeting Chinese standard GB2626-2006) and Europe (FFP2, meeting European standard EN 149-2001).

As imported masks flooded the U.S. market, the CDC and FDA were unprepared to rapidly assess the quality of individual products. Health care systems, first responders, and others have received donations of unfamiliar mask models, many of them donated, and with unclear supply chain provenance. In an effort to clarify matters, the CDC released a list of authorized respirators under the EUA (Appendix A) on April 3, 2020 (U.S. Food and Drug Administration, 2020a). No performance testing data was required from respirator manufacturers to corroborate performance claims before inclusion on the list. In the ensuing weeks, the CDC noted a dramatic increase in counterfeit respirators that misrepresented NIOSH approval, and the CDC and other groups revealed that some respirators labeled as N95, KN95, or FFP2 fail to perform as expected for filtration and fit (Centers for Disease Control and Prevention, 2020). Appendix A has been revised several times since it was first published, creating uncertainty among state officials and hospital administrators as to which face masks are safe for use — particularly for masks labeled KN95. A recent study of donated FFRs of unknown provenance demonstrated variable performance, with no clear standards for identifying legitimate products (Plana et al., 2020).

Reuse and sterilization. As national PPE shortages emerged, methods were developed for sterilizing and reusing PPE. During the COVID-19 pandemic, the FDA issued EUAs for these methods. For instance, Battelle received an EUA on March 29, 2020, for its vaporized hydrogen peroxide sterilization system, on the same day President Donald Trump tweeted about the product at the behest of Ohio Governor Mike DeWine. The company was subsequently awarded a federal contract of $400 million on April 13, 2020, to sterilize N95 masks. Battelle facilities that could sterilize up to 80,000 masks per day at full capacity were established across the country, but at a cost of $3.25 per mask that did not include transportation to and from the facility. By comparison, the baseline pre-pandemic cost of an N95 mask was approximately $1. The rollout did not go well: by June 2020, the company had billed the federal government $78 million, which amounted to more than $110 per sterilized mask. In October, the FDA sent a warning letter to Battelle regarding its inadequate procedures for identifying adverse events.

In contrast, a similar product, Steramist (using ionized hydrogen peroxide, or iHP), has been shown to sterilize masks as effectively as the Battelle system (Cramer et al., 2020). The Steramist environment chamber is more readily available in animal research facilities at academic medical centers, which allows institutions (like the Dana-Farber Cancer Institute in Boston) to decontaminate its own PPE. Quite unlike Battelle's quick path to an EUA, the manufacturer of Steramist, TOMI Environmental Solutions, applied for an EUA for Steramist in April 2020 but has yet to receive authorization. Other companies have had more success in obtaining EUAs, but it is unclear how routinely these processes are being used given pushback from health care workers averse to wearing "dirty" PPE.

Alternatives to N95 masks: Powered Air-Purifying Respirators. Powered air-purifying respirators (PAPRs) are perhaps the most complex of all respiratory PPE. They supply filtered air to the user while preventing exposure to external air; no FFP is needed. PAPRs have historically been in short supply in hospitals: PAPRs are expensive, bulky, loud, and have short battery life, but in times of PPE shortage may be sustainable alternatives to N95s. Under NIOSH regulation, medical PAPRs are held to the same standards as PAPRs intended for other uses, which are that the device have a P100 rating (oil-**P**roof, **100**% filter efficiency), a higher standard than N95 masks. No novel PAPRs have received an EUA to date, and it is not clear whether such devices could be made available through an EUA in the absence of NIOSH certification.

Recommendations for Action

Federal government:

- ASPR should immediately and substantially increase the Strategic National Stockpile of traditional and alternative PPE while developing an equitable national dissemination strategy for PPE dissemination to states.
- Congress should pass President Biden's $1.9 trillion COVID-19 relief plan, which calls for an additional $30 billion toward a Disaster Relief Fund, earmarked for supplies and PPE.
- Congress should fund research into more sustainable forms of PPE, including "biological N95 masks" designed for sterilization and reuse. Biomedical Advanced Research and Development Authority (BARDA) and Defense Advanced Research Projects Agency (DARPA) may be best suited to conduct such research, so long as any PPE-related innovation from these agencies is not held in confidence as a state secret.
- The FDA should require that manufacturers more comprehensively evaluate products or processes that have received EUAs and should revoke EUAs for which supplementary data fall short of appropriate regulatory standards. The FDA should update PPE-related guidance in the following areas: (1) a finalized "Appendix A" list of authorized respirators; (2) an amended EUA on imported face masks that penalizes identifiable manufacturers of counterfeit products under the agency's misbranding authority; and (3) guidance as to the role of FDA and NIOSH in testing newly fabricated PAPRs.

State governments:

States should:

- establish permanent channels for sourcing traditional and alternative PPE in times of crisis, independent of federal authorities, and ensure those channels remain viable over time;
- and establish state PPE stockpiles or engage in long-term procurement contracts, while ensuring equitable distribution of PPE during public health crises, rather than a system based on prestige, financial resources, or political capital.

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COVID-19 as an Example of Why Genomic Sequence Data Should Remain Patent Ineligible

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SUMMARY. The researchers who determined the genomic sequence of the SARS-CoV-2 virus did not seek to patent it, but instead released it in the publicly-accessible GenBank data repository. Their release of this critical data enabled the scientific community to mobilize rapidly and conduct research on a range of diagnostic, vaccine, and therapeutic applications based on the viral RNA sequence. Had the researchers sought patent protection for their discovery, as earlier research teams had during the SARS, H1N1 and H5N1 outbreaks, global research relating to COVID-19 would have been less efficient and more costly. One of the reasons that patents are no longer sought on genomic sequences is the U.S. Supreme Court's decision in ***Association for Molecular Pathology v. Myriad Genetics, Inc.***, which established that a sequence of naturally-occurring nucleotides is an unpatentable "product of nature" (***Association for Molecular Pathology v. Myriad Genetics, 2013***). Yet, in the midst of the COVID-19 crisis, patent advocates are calling on Congress to overturn the Myriad decision and once again allow patenting of genomic sequences. This Chapter argues that the COVID-19 pandemic illustrates why the "product of nature" exclusion under patent law, which prevents the patenting of genomic sequence data, should be preserved and strengthened under U.S. law.

Introduction

From the beginning of the COVID-19 pandemic, governments, health care advocates, and scholars around the world expressed concern that patents could slow the manufacture and distribution of medical supplies, equipment, vaccines, and therapies to populations most in need of them. Chapter 21 of *Assessing Legal Responses to COVID-19: Volume I*, discusses potential policy responses to these concerns, including the exercise of government use rights, the imposition of access conditions on research funding and public procurement, and the encouragement of patent pools. Yet amidst the debate over patents relating to the pandemic response, one significant discovery has remained free from patent claims: the genomic sequence of the SARS-CoV-2 virus itself.

Genomic Patents in the United States

The genomic RNA sequence of SARS-CoV-2 (the viral infectious agent responsible for COVID-19) was first elucidated in January, 2020, by a team of 19 researchers at four Chinese universities and public health agencies. They published their findings in the journal *Nature* and released the sequence to the publicly-accessible GenBank database maintained by the U.S. National Center for Biotechnology Information (Wu et al., 2020). The SARS-CoV-2 sequence and its many emerging variants have proved invaluable to research concerning the virus. Yet these sequences are not known to be subject to any pending or issued patent claims and are thus available without restriction to public and private researchers around the world.

Myriad and Products of Nature

One reason that the SARS-CoV-2 sequence has not been patented, at least in the United States, is due to the U.S. Supreme Court's decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, which established that a sequence of naturally-occurring nucleotides is an unpatentable "product of nature" (technically, the case related to DNA rather than RNA sequences, but the Court's reasoning applies to both molecules with equal force) (*Association for Molecular Pathology v. Myriad Genetics*, 2013). While the Court held that patents might be available on "new applications of knowledge," genes themselves, and their nucleotide sequences, are ineligible subject matter for patent protection.

Legislative Efforts to Overrule Myriad

The *Myriad* decision, together with the Supreme Court's earlier decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, have been portrayed as effectively eliminating the possibility of patents for genetic diagnostics — a potentially devastating result for the diagnostics industry (Eisenberg, 2015; *Mayo Collaborative Services. v. Prometheus Laboratories, Inc.*, 2012). As a result, advocates of stronger patent protection have steadfastly sought to

overturn the *Myriad* and *Mayo* decisions through legislative means. In 2019, Senators Chris Coons and Thom Tillis introduced legislation that would have abrogated any "implicit or judicially created exceptions to [patent] subject matter eligibility including 'abstract ideas,' 'laws of nature,' or 'natural phenomena.'" The effect of these provisions would have been to permit, once again, the patenting of any previously undiscovered natural substance or genomic sequence.

In addition to genetic data, the Coons-Tillis proposal sought to address the patentability of other controversial inventions including software, medical diagnostic methods, and methods of conducting business. As a result, opposition arose from numerous quarters. Notably, 160 civil rights, medical, scientific, patient advocacy, and women's health organizations openly opposed the Coons-Tillis bill, arguing that if the bill were enacted, "Patients will again be at risk of lacking access to information about their genes, about their very selves. We likely will again see high prices for tests with no competition in the market, and harms to innovation and useful research with no guarantee that the law would eventually provide the same protections that it now offers" (American Civil Liberties Union et al., 2019). The Senate Judiciary Committee held three sets of hearings on the bill in 2019, after which the draft legislation stalled.

Despite the failure of this legislative attempt to reverse the *Myriad* decision, the emergence of the COVID-19 pandemic in early 2020 led to renewed calls for increased patent protection of biomedical discoveries. Thus, at the same time that advocates and governments around the world were calling for the relaxation of patent restrictions to address the supply of critical supplies and equipment in response to the pandemic, patent advocates blamed the lack of reliable diagnostic tests, vaccines, and treatments for COVID-19 on too little patent protection. Senator Tillis commented in one interview, "The way the current jurisprudence sits, there's almost no incentive to develop new, innovative diagnostic testing methods or other life-saving treatments. As the COVID-19 pandemic is unfortunately showing us, having these tests in the pipeline are crucial for public and economic health, well-being, and safety" (Quinn, 2020).

During the course of the pandemic, the U.S. Patent and Trademark Office (PTO) introduced new programs to accelerate the examination and issuance of patents covering COVID-19 related inventions, and Senator Ben Sasse introduced legislation that would, among other things, add 10 years to the term of COVID-related patents (Facilitating Innovation to Fight Coronavirus Act, 2020).

In early 2021, new legislative proposals to strengthen patents, including by Senators Tillis and Coons, began to percolate as the Biden administration prepared to take office. Yet despite unsubstantiated claims that increased patent protection would have facilitated the speedier development and deployment of COVID-related diagnostics, vaccines, and therapies, there is ample evidence to suggest that, at least in the case of genomic sequences, a return to the days of patenting would have been counterproductive.

The Value of Open Genomic Data

The Genomic Commons

Since the Human Genome Project (HGP) (1988-2003), the field of genomic research has been characterized by norms of international collaboration and data sharing. Explicit patent deterrence strategies were embodied in the data sharing policies adopted by the governmental and philanthropic funding agencies that supported this research, resulting in a vast aggregation of genomic data that is available to researchers around the world — the "Genomic Commons" (Contreras & Knoppers, 2018). Contributions to this public store of knowledge were made not only by governmental and academic laboratories, but by pharmaceutical and biotechnology companies (Contreras & Knoppers, 2018). Research has shown that the public availability of genomic data from the HGP has significantly enhanced scientific research as compared to data that is maintained as proprietary (Williams, 2013).

The Gene Patenting Race

Despite the growth of the public genomic commons, a countervailing trend emerged in the late 1980s and early 1990s toward private patenting of genomic discoveries. The patents issued to Myriad Genetics covering the BRCA1 and BRCA2 genes, which are linked to familial breast and ovarian cancer, were examples of this growing phenomenon. By 2005, two MIT researchers estimated that a full 20% of known human genes were covered by patents (Jensen & Murray, 2005). While the PTO rejected the patentability of short DNA segments having unknown utility, larger segments of DNA constituting full genes were deemed to be patentable as new "compositions of matter" (Sherkow & Greely, 2015).

The Virus Patent Races

Patents during this period were not limited to human genomic sequences. Nucleotide sequences of plants, model organisms, bacteria and viruses were also being patented. As documented by Queensland University of Technology professor Matthew Rimmer, a contentious international "race" to identify and patent the RNA sequence of the SARS virus occurred shortly after the outbreak of the epidemic in 2002 (Rimmer, 2004). Research institutions in North America, Europe, and Asia each rushed to file patent applications "broad enough to allow their holders to claim rights in most diagnostic tests, drugs, or vaccines that have been or would be developed to cope with the outbreak" (Rimmer, 2004). Among the negative outcomes of this patenting race was the emergence of a patent "thicket" in the area of SARS research and the unsuccessful attempt to pool these patents for broader use (Beldiman, 2012). Similarly dysfunctional scenarios played out a few years later with the H1N1 and H1N5 influenza outbreaks (Greene, 2010; Beldiman, 2012).

Unlike these prior outbreaks, there does not appear to have been a rush to patent the SARS-CoV-2 genomic sequence. This lack of patenting is due both to the rapid public release of the sequence by the researchers who first identified it (i.e., acting as prior art to defeat patents that might later be filed (Contreras & Knoppers, 2018)) and the presumption against genomic sequence patents

established in the United States by the *Myriad* decision. This "patent free zone" enabled rapid international collaboration on basic research concerning COVID-19.

Why Patents on Genomic Sequences Should Not, and Need Not, Be Allowed

Despite vociferous calls for more patenting of technologies pertinent to COVID-19, Congress should resist legislative attempts to overrule the *Myriad* decision and its ban on patenting genomic sequence information.

Genomic Sequence Data is a Basic Research Tool that Should be Broadly Available

A vast array of basic scientific research is enabled by knowledge of an organism's genomic sequence. This research can lead to a better understanding of biochemical mechanisms and to medical innovations such as vaccines and therapeutics. As such, genomic sequence data are a form of basic "research tool" — a resource that can be used by multiple researchers to address different research questions. There is a broad policy consensus that research tools should be made as broadly available as possible to the research community (National Institutes of Health, 1999). Allowing one or a handful of entities to own this basic scientific information can hinder research when speed and international collaboration are needed most. Studies have shown that researchers were reluctant to study the patented BRCA genes, thereby reducing overall knowledge and scientific advancement, something that cannot be afforded in the face of an emergent global pandemic.

Composition of Matter Patents Preempt all Uses of a Sequence

Because patents can claim genomic sequences as new "compositions of matter" (like polymers or metallic alloys), they preempt all possible uses of the patented sequences, whether or not envisioned by the patent holder (Contreras, 2020). The Supreme Court correctly recognized in *Myriad* that genomic sequences of biological organisms are not new forms of matter, even if they are isolated and purified in the laboratory. Reversing this holding would again allow individual patent holders to control all uses of a particular genomic sequence, thereby creating significant bottlenecks to effective research and development and granting patent holders a windfall with respect to applications of a discovery that they did not actually make.

Composition of Matter Patents Discourage Improvements

Because broad composition of matter patents cover all uses of a patented gene or variant, any improvement to a diagnostic test that the patent holder makes will likely be covered by its own patents. And because competitors are not permitted to offer competing diagnostic tests, a patent holder has little incentive to improve its own diagnostic tests once a patent is issued. That is, its broad patent is likely to cover both the original and improved tests, and no competing tests are allowed, giving the patent holder little motivation to improve the tests over which it already has monopoly control.

Patents Are Not Needed to Incentivize the Discovery of Genomic Sequences

As noted above, today a vast body of human and non-human genomic sequence data is available to researchers in public repositories (Contreras & Knoppers, 2018). The discovery of this data was largely supported by government and philanthropic funding sources. With advances in sequencing technology and a global recognition that genomic sequence data represent a scientific resource for all, the sequencing of new biological entities such as emergent viral strains can be, and is, accomplished quickly and efficiently through existing government-funded programs. The sequencing of the SARS-CoV-2 virus by a coalition of Chinese university and public health agencies (Wu et al., 2020), with no attempt to patent their results, demonstrates this reality. Since then, substantial scientific advances have been made as new variants and mutations of the SARS-CoV-2 virus have emerged during the course of the pandemic. As such, arguments that patenting is required to induce private actors to invest in this work are simply not applicable to the derivation of genomic sequence data today.

There is Ample Opportunity for Patent Protection of Medical Innovations Without Claiming Genomic Sequences

A large number of patents exist and continue to be obtained on innovations relating to COVID-19, including protective equipment, medical devices, tracing and modeling algorithms, diagnostic kits, vaccines, and therapeutics (Tietze et al., 2020). As such, ample private incentives — both in terms of patent royalties and procurement payments — exist to promote the development of needed technologies like these. Basic genomic structures, however, are research tools, not products or product components. As such, allowing them to be patented does no more than enable the holders of those patents to impose a tax on the industry that is developing products that rely on this basic scientific information. Had the basic genomic sequence of the SARS-CoV-2 been patented, as had the sequences of the SARS, H1N1 and H1N5 viruses, the development of desperately needed vaccines and therapies would have been delayed or, at best, made more costly to consumers and health care providers.

Patents on Genomic Sequences Increase Costs and Reduce Access to Medical Innovations

Myriad Genetics priced its genetic tests at a level beyond the means of many individuals, leading to widespread criticism of the company and the patents that gave it a monopoly over testing the BRCA1/2 genes. Issues surrounding access to genetic testing thus lay at the heart of the *Myriad* litigation. The issue of access was central to the American Civil Liberties Union, which brought the case, and its recruitment of numerous patient advocacy groups, health care providers, and medical societies as plaintiffs and *amici curiae* (Contreras, 2020). The Supreme Court's decision invalidating most of Myriad's gene patents was widely heralded as a victory for health care access. A return to the days of genomic sequence patents would reverse this victory and again enable private firms to wield legal exclusivity to increase patient costs, burden the health care system, and exclude those most in need from critical medical innovations.

Recommendation for Action

Federal government:

- Congress should reject legislative proposals that seek to overrule the ban on patenting naturally-occurring genomic sequences that was established by the Supreme Court in *Association for Molecular Pathology v. Myriad Genetics, Inc.*

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Drug and Vaccine Development and Access

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SUMMARY. This chapter explains how COVID-19 drugs and vaccines reach the market in the United States. As is always true, drug and vaccine manufacturers may seek U.S. Food and Drug Administration (FDA) approval of their products via traditional mechanisms, and pre-approval access may be granted under the expanded access or right to try pathways. In a public health emergency like COVID-19, an additional mechanism is also available: Emergency Use Authorizations (EUAs). This Chapter (1) assesses how FDA has used its EUA authorities for COVID-19 drugs and vaccines thus far, (2) considers how FDA has balanced the need for robust evidence of safety and effectiveness for COVID-19 products against the urgent need to speed patients' access amid the clinical and political realities of the pandemic, and (3) highlights additional considerations specific to vaccines. The Chapter concludes with recommendations for policymakers and regulators at the federal and state levels, intended to improve public understanding of the regulatory process for COVID-19 drugs and vaccines, protect scientific decision making from undue political pressure, and ensure that manufacturers develop robust evidence of safety and effectiveness — and ultimately safe and effective COVID-19 countermeasures.

Introduction

This section briefly explains the typical regulatory processes for FDA approval of drugs and vaccines and for non-trial pre-approval access for seriously ill patients. It then explains the additional EUA mechanism that is available during public health emergencies, such as the COVID-19 pandemic. Although FDA is the primary gatekeeper for drugs and vaccines, this section highlights that states also play a role through their authority to regulate medical practice. Further discussion of FDA and state regulatory processes and roles is provided in *Volume I*.

FDA Approval and Pre-approval Access

Before a new drug or vaccine may be distributed in U.S. interstate commerce, FDA must approve the product as safe and effective for its intended use. To make the necessary showing of safety and effectiveness, manufacturers typically generate significant information about their products through pre-clinical testing and three phases of clinical trials in humans. Although this process can take substantial time, it is critical for public health because it helps protect people from unsafe or ineffective products and ensure that necessary information about drugs' and vaccines' effects is generated, which, in turn, incentivizes the development of products that actually work (Eisenberg, 2007).

There are, however, ways that patients can access products for uses that FDA has not approved, or products that are not FDA-approved for any use. Once FDA has approved a product for one use, health care professionals are often free to prescribe and dispense it for any use, including unapproved uses (known as "off-label" uses). Additionally, in certain circumstances manufacturers may provide patients wholly unapproved, experimental products outside of clinical trials for treatment purposes. One such form of non-trial pre-approval access is "expanded access," which requires FDA authorization among other things, and another is the Right to Try Pathway, created by Congress in 2018, which does not require FDA authorization.

These processes for drugs and vaccines remain available during public health emergencies. Manufacturers may seek FDA approval for drugs or vaccines for COVID-19. For example, in October 2020 FDA approved Gilead Sciences' drug, remdesivir, to treat COVID-19 patients requiring hospitalization (this approval followed use of the drug under an EUA). Likewise, manufacturers may provide COVID-19 patients non-trial pre-approval access to experimental products through the Right to Try Pathway or expanded access — which is how many patients received convalescent plasma, and President Trump received an antibody drug when hospitalized with COVID-19, before FDA issued EUAs for those products. Health care

professionals also generally may prescribe and dispense already-approved products for COVID-19. For instance, a long-approved corticosteroid, dexamethasone, has been used off-label based on research suggesting it can reduce mortality in certain COVID-19 patients.

FDA's Power to Issue EUAs During Public Health Emergencies

In addition to the above-outlined mechanisms, in 2004 Congress created the EUA pathway by adding Section 564 to the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. § 360bbb-3). This provision allows FDA to issue EUAs authorizing the distribution of unapproved medical products, or unapproved uses of already-approved products, when the Secretary of the Department of Health and Human Services (HHS) determines there is a "public health emergency, or a significant potential for a public health emergency." Although patients generally can access already-approved products for off-label uses without an EUA, the federal government could not distribute products for off-label uses through the Strategic National Stockpile, and liability protections for manufacturers and health care professionals under the Public Readiness and Emergency Preparedness Act may not be available.

For FDA to issue an EUA, whether for an unapproved product or an off-label use of an approved product, various criteria must be met. These include that the manufacturer show "it is reasonable to believe" "the product may be effective" for the relevant condition — a bar that is decidedly lower than the "substantial evidence" of effectiveness required for FDA approval. FDA may impose restrictions on products through EUAs, including requiring information collection through patient registries or restricting who may administer the product and to what categories of patients. EUAs are time-limited—they only remain in effect during the public health emergency. Additionally, the FDCA requires FDA to "periodically" review existing EUAs and authorizes FDA to revoke or revise EUAs at any time if appropriate to protect public health or safety. FDA, thus, has broad power to shape how products distributed under EUAs are used, and can change conditions or revoke permission to distribute more easily than it can for approved products.

FDA typically decides whether a product meets approval or authorization standards and determines any conditions on authorization. Given the political nature of responses to public health emergencies, however, it is important to understand that FDA is an agency within HHS, and federal law expressly authorizes the Secretary of HHS — and not FDA — to make these decisions. The secretary delegates that decision-making authority to FDA and rarely has overridden FDA decisions about product authorization. But in 2020, the Trump administration exerted significant pressure on FDA to rush the authorization of COVID-19 drugs and vaccines, leading to renewed calls to protect FDA independence (Califf et al, 2020).

The States' Role

States also play various roles in determining product access and helping patients and health care professionals understand what is known about product safety and effectiveness. For example, in March 2020, there were concerns about shortages of chloroquine and hydroxychloroquine — drugs approved for malaria, lupus, and rheumatoid arthritis, but that were being hyped at the time for COVID-19 and hoarded by physicians, despite a lack of reliable evidence demonstrating their effectiveness. In response, some states (and the District of Columbia) used their authority to regulate medical practice to limit off-label prescribing or dispensing of the drugs for COVID-19 and communicated the lack of evidence demonstrating their effectiveness for COVID-19.

States might also try to use their authority over medical practice to permit access to products that lack any FDA authorization or to completely prohibit use of FDA-authorized COVID-19 products. Indeed, in fall 2020 several states, including New York, established independent review committees for COVID-19 vaccines due to concerns about political interference with FDA's process. As of February 2021, however, no state has attempted to prohibit any FDA-authorized COVID-19 vaccines. Any such efforts would raise questions about preemption, while state laws or regulations more permissive than federal ones may be without practical effect, as states cannot eliminate applicable federal requirements (Zettler, 2017).

Importantly, states also have a role in vaccine allocation, distribution, and administration. Due to limited vaccine supply, the Centers for Disease Control and Prevention (CDC) issued non-binding guidance on priority-access categories, and many states re-worked the priority access hierarchy. Moreover, each state has determined which hospitals, clinics, providers, and pharmacies have access to vaccines, and how many doses will be allocated to each. Particularly because FDA does not consider equity when determining the scope of an EUA, states, local governments, and these private institutions are largely responsible for ensuring equitable allocation (Persad, 2021). Additionally, no state has issued a COVID-19 vaccine mandate, and several experts (including one of the authors) have noted that such mandates, for products under EUAs, would be illegal and unethical (Parasidis & Kesselheim, 2021).

Assessing the Regulatory Approach during the COVID-19 Pandemic

In a global public health emergency, like the COVID-19 pandemic, FDA is faced with an undeniably difficult task. On one hand, developing rigorous evidence of products' safety and effectiveness is no less important — rather it is equally, if not more, important (London & Kimmelman, 2020). Generating this evidence will take time. Non-trial pre-approval access, including via EUAs, has the potential to interfere with this necessary evidence generation by making it difficult to enroll participants in clinical trials. On the other hand, there is an urgent need to move quickly. The addition of the EUA mechanism to the FDCA arguably reflects a societal decision that FDA ought to have flexibility to lower standards of safety and effectiveness during public health emergencies to speed access to promising, but unproven, products. FDA is likely to face tremendous political pressure — whether from the White House, HHS, Congress, industry, patients, or other stakeholders — to use that flexibility, and may lose public trust if the agency is viewed as either unresponsive to patients' concerns or as moving too quickly to authorize access to countermeasures based on insufficient data.

This Section examines how FDA has balanced these sometimes-competing societal interests and operated amid these political realities during the COVID-19 pandemic thus far.

Balancing Evidence and Access

The federal government, including FDA, has taken some beneficial steps to exercise flexibility and proactively speed the development of promising COVID-19 drugs and vaccines. For example, "Operation Warp Speed," a public-private partnership of industry and government representatives working together on product development, is credited with helping to make possible the remarkably efficient development of COVID-19 vaccines. FDA also has issued dozens of guidance documents on drugs and biological products for COVID-19, to help clarify what is needed to bring a product to market. Additionally, FDA has made use of the flexibility that the EUA mechanism offers by issuing, revising, and revoking EUAs. As of February 14, 2021, the agency has issued seven EUAs for drugs to treat COVID-19 and two EUAs for COVID-19 vaccines. It revoked two of the drug EUAs, for hydroxychloroquine and chloroquine, on June 15, 2020, and has revised numerous EUAs. As a final example, FDA has taken steps to improve transparency as the pandemic has evolved, committing in November 2020 to proactively make public its reviews of data and information supporting decisions to issue, revise, or revoke drug and biological product EUAs. Such transparency can help the public understand the agency's reasoning and what is known about the safety and effectiveness of COVID-19 countermeasures, as well as encourage public trust in agency decision-making.

At the same time, there is room for improvement, particularly with respect to public understanding of EUAs, implementation of FDA's EUA authorities, and providing equitable access to COVID-19 countermeasures. Although FDA generally distinguishes between EUAs and approvals in its communications, some media reports continue to equate EUAs with FDA approval. Even for those EUAs based on more robust evidence, such as the December 2020 vaccine EUAs based on evidence that the products reduce symptomatic cases, it remains critical to understand that EUAs are a form of pre-approval access, and products issued EUAs are not necessarily safe or effective COVID-19 countermeasures. Misunderstandings about what an EUA signifies could drive inappropriate policy decisions or undermine public trust in FDA decisions when products issued EUAs prove ineffective or unsafe.

Another major concern is that FDA, perhaps driven by political pressure, may too freely issue EUAs for COVID-19 countermeasures, even judged against the relatively low statutory standard for issuing EUAs. The now-revoked EUAs for hydroxychloroquine and chloroquine provide apt examples. That the EUAs were ultimately revoked is not in and of itself troubling. Because the EUA mechanism permits FDA to authorize products with less evidence than is required for approvals, we should expect that FDA will authorize products that, once on the market, no longer meet the criteria for an EUA (or ultimately prove unsafe or ineffective). FDA should revoke EUAs when evidence warrants it — a revocation reflects the uncertainty surrounding safety and effectiveness of countermeasures that receive an EUA, along with the iterative nature of EUA issuance and oversight. In the case of hydroxychloroquine and chloroquine, however, FDA's original decision to issue the authorizations rested on a particularly shaky foundation: limited data of effectiveness from one randomized pilot study of 30 subjects that found little to no effect of the drugs in COVID-19, and an open-label, non-randomized study in 26 subjects that was later discredited, balanced against several known serious risks of the drugs, which were already approved for other uses. FDA issued the EUAs only nine days after the president publicly touted the drugs as COVID-19 countermeasures and, according to a whistleblower complaint from the former director of the Biomedical Advanced Research and Development Authority, at the Secretary of HHS's direction — raising significant concerns about inappropriate political interference. Similar concerns were raised about FDA's August 2020 decision to issue an EUA for convalescent plasma as well as about agency officials dramatically overstating the evidence supporting that product's effectiveness (Sachs, 2020). In February 2021, FDA revised the EUA for convalescent plasma to restrict its use to a subset of hospitalized patients, based on the agency's ongoing evaluation of the evidence supporting the product's use for COVID-19.

Yet another major concern is how to provide equitable access to COVID-19 countermeasures once they are issued an EUA or approved. For example, the CDC's Advisory Committee on Immunization Practices and an ad hoc committee of the National Academies of Sciences, Engineering, and Medicine and the National Academy of Medicine have offered recommendations for equitable vaccine distribution. Many aspects of product access, such as ensuring the affordability of countermeasures and developing logistical arrangements for fair distribution, generally fall outside FDA's purview and likely require intragovernmental and cross-sector coordination. But, there are steps that FDA might take to use the authorities that it does have to further the goal of equitable access. For instance, Sarpatwari and colleagues argued that FDA could have required a registry for remdesivir that collects information on patient demographics (among other things) when that drug was under an EUA, to enable better tracking of access disparities (Sarpatwari et al., 2020).

Special Considerations for Vaccines

COVID-19 vaccine EUAs pose many of the same issues as those posed by drug EUAs, as well as additional issues specific to vaccines. A drug that is issued an EUA is typically administered to a sick person with no other treatment options, whereas a vaccine is administered to a healthy person. This difference in health status alters the ethical and clinical risk-benefit calculus. A COVID-19 vaccine also may be used widely across the population in individuals of varying ages and co-morbidities. Moreover, COVID-19 vaccines are used against the background of existing vaccine hesitancy, making creating and maintaining public trust in FDA's decision-making more difficult (Parasidis, 2016).

Vaccine research and development, like drug research and development, generally takes time. Most vaccines take a decade or longer to develop. Before the COVID-19 vaccines, the quickest vaccine to come to market was the mumps vaccine, which took four

years from the time virus samples were collected to FDA approval. Death or serious side effects from a COVID-19 vaccine could cause panic among the public and drive people away from vaccination — particularly if the vaccine were not supported by robust evidence demonstrating its safety and effectiveness. Although not perfectly analogous, one worthwhile example to consider is the 1976 swine flu vaccination program. The swine flu vaccine was rushed to market to address a public health emergency. Although an outbreak of swine flu did not materialize, the vaccine itself caused dozens of deaths and thousands of vaccine-induced injuries, including paralysis (Parasidis, 2017).

For all of these reasons, developing rigorous evidence of safety and effectiveness, developing such evidence across all sub-populations for which a vaccine is intended, and being transparent about the basis for agency decisions is particularly critical before distributing a COVID-19 vaccine. Consistent with this idea, FDA has taken steps to assure that vaccine EUAs are supported by robust evidence and to reassure the public about the agency's scientific standards, notwithstanding numerous instances of inappropriate political pressure during the Trump administration, including threats to fire the FDA Commissioner (Califf et al., 2020). In summer and fall 2020, FDA issued guidance documents on COVID-19 vaccines that emphasize the importance of large, randomized clinical trials. Before issuing any COVID-19 vaccine EUAs, FDA also held advisory committee meetings in October and December 2020, on COVID-19 vaccine development generally as well as on each specific vaccine candidate for which the agency had received requests for EUAs. These meetings, which were public, as required by law, provided FDA an opportunity to obtain outside experts' input and to make transparent more information about the scientific evidence supporting COVID-19 vaccines before making any decisions on particular EUAs. In December 2020, FDA ultimately issued EUAs for Pfizer/BioNTech and Moderna's COVID-19 vaccines, both of which were supported by evidence of safety and effectiveness. But there also were significant gaps in the data. Neither vaccine was examined for preventing asymptomatic infection and transmission, which is important because at least 40% of COVID-19 cases are asymptomatic and transmission from asymptomatic individuals constitutes more than 50% of COVID-19 transmissions. Vaccine safety was tracked for only two months, a period that is far shorter than for any other vaccine. Indeed, days after authorization, serious adverse events caused a warning to be issued to advise against vaccination for individuals with severe allergies. Moreover, it is not yet clear whether FDA included conditions in the EUAs adequate to ensure that vaccine access under EUAs does not thwart continued research on the authorized vaccines, as well as on other vaccine candidates in development.

Although as of February 2021 the demand for the authorized vaccines appears to outstrip current supply, in our view, it is critical that vaccinations with products under EUAs be entirely voluntary. As discussed above, the FDCA precludes government mandates for vaccines distributed under EUAs (Parasidis & Kesselheim, 2021). Even if, as some have suggested, the FDCA does not preclude employer and other private mandates for EUA vaccines, such mandates would be unethical and counterproductive to public health strategies encouraging vaccination (Rothstein et al, 2021). Moreover, should a COVID-19 vaccine ultimately receive full approval, this alone should not be viewed as sufficient to trigger mandates. Rather, mandates should be viewed as a last resort and used only if several other measures are first exhausted and appropriate risk mitigation procedures have been implemented, including but not limited to an adequate system of compensation for vaccine-related injuries (Halabi et al., 2020; Mello et al., 2020).

Recommendations for Action

Federal government:

- FDA should clearly communicate and reiterate that EUAs are not approvals and that the legal standard for issuing an EUA does not include a determination that the product has been shown to be safe or effective for its intended purpose.
- For all decisions that FDA makes about COVID-19 countermeasures, the agency should be as proactively transparent as the law permits it to be, consistent with its November 2020 commitment.
- Congress and FDA should consider creating specific processes to protect decision-making during pandemics, such as requiring FDA to proactively release detailed information about the bases for its EUA decisions immediately after they are made. Additionally, Congress should consider whether FDA should be a stand-alone agency, outside HHS.
- FDA should issue EUAs judiciously. The FDCA permits, but does not require, FDA to issue an EUA when the specified criteria are met. The agency retains flexibility to determine that an EUA is not appropriate for the public health even when all statutory criteria are met.
- FDA should consider routinely requiring patient registries for products that are issued EUAs to help gather information both about patient outcomes and about any disparities in access to such products (Sarpatwari et al., 2020).
- FDA should pay particular attention to the risk that an EUA for a drug or vaccine will delay further research with that product as well as potential competitor products, and design the scope of and conditions on EUAs to prevent such outcomes to the extent possible.
- Consistent with its obligations under Section 564 of the FDCA (21 U.S.C. §360bbb-3), FDA should actively and carefully review EUAs, revoking or revising them when needed. The rationale for the timing of such post-market reviews should be data-driven and publicly disclosed. The results of FDA's reviews, coupled with a summary analysis of data, also should be made public as soon as they are completed.
- Unless COVID-19 vaccine EUAs are (1) supported by safety and effectiveness data sufficient to allow approval of a biologics license application (BLA) and (2) necessary as a stopgap to allow time to prepare, review, and approve a BLA, FDA should decline to authorize such EUAs. Particular attention should be paid to whether an EUA for a vaccine that can be used across the entire population may create unnecessary risks to healthy individuals and may delay or prevent clinical trials.
- Congress should consider whether establishing the same statutory standard for EUAs for drugs, intended to treat seriously ill patients without other options, and for vaccines, intended for widespread use in healthy people, is appropriate and whether revisions to Section 564 of the FDCA (21 U.S.C. § 360bbb-3) are needed.

State governments:

- State officials and agencies, including boards of medicine and pharmacy and public health departments, should clearly communicate to health care institutions, health care professionals, and the public the difference between EUAs and FDA approvals, and what is known, and not known, regarding the safety and effectiveness of products available under EUAs.
- State boards of medicine and pharmacy should discourage off-label use of existing products unless strong evidence supports use for COVID-19.
- States should not issue COVID-19 EUA vaccine mandates.
- Particularly given FDA's efforts to improve the transparency of its COVID-19 drug and vaccine reviews, any states with plans for independent vaccine review committees should reconsider such efforts.

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Assuring Essential Medical Supplies During a Pandemic: Using Federal Law to Measure Need, Stimulate Production, and Coordinate Distribution

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SUMMARY. It was known before the emergence of COVID-19 that a pandemic would produce harmful shortages of personal protective equipment (PPE) and other essential resources. Training exercises had exposed depleted stockpiles, fragile global supply chains, and confusion about the basic responsibilities of key government agencies. These findings did not lead to corrective action, and when the shortfalls hit in spring 2020, the Trump administration failed to implement a coherent strategy in response. The result has been chaotic and inefficient, with continuing competition for scarce supplies among states, health systems, and smaller entities like nursing homes, prisons, and schools. The Biden administration has not only committed to mounting a successful vaccination campaign, but also to ensuring an adequate supply of essential medical supplies and pharmaceuticals to protect health care workers and enable schools and other venues to reopen safely. Incoming officials have suggested that they will rely on the Defense Production Act (DPA), federal purchasing power, and financial support for innovation to stimulate production, strengthen supply chains, coordinate expertise, and resolve market failures. This is a welcome sign. There is plenty of low-hanging fruit to pick, but systemic challenges cannot be resolved quickly. This Chapter recommends the use of federal legal authority to (1) make large purchase commitments to domestic producers; (2) require ongoing reporting of key PPE and other supply inventory as a condition of CMS reimbursement; and (3) restate the mission of the Strategic National Stockpile (SNS) to serve as both a reservoir of essential supplies for the nation and a coordinating center for tracking inventory in the public and private sectors. We also recommend an independent commission to investigate how to improve domestic production and emergency distribution of PPE, medicines and other essential medical products.

Introduction

For years, there had been warnings that a pandemic would produce immediate and harmful shortages of PPE and other medical supplies. A federal simulation in 2019 demonstrated that key products would become scarce as demand surged and global supply chains broke down. That exercise also showed that state and federal officials were unclear about their authority and responsibility to forge an effective response. These findings were eerily prescient and roundly ignored. The country entered the COVID-19 pandemic without an infrastructure of applicable supply chain expertise and monitoring data, or even an administrative unit ready to take on the essential supplies challenge.

When shortages and panicked confusion emerged in February 2020, the Trump administration failed to rapidly create an inventory system for PPE and other essential supplies, or to coordinate purchasing and distribution. The administration often competed against states or encouraged states to compete against each other. Its forays into distribution were harmful. For more information, please see Chapter 23 in *Assessing Legal Responses to COVID-19: Volume I*.

As spring gave way to summer, the Trump administration took some important action on production. Between March 2020 and August 2020, the administration used its DPA authority 43 times to expedite contracting or invest in production capacity. These actions helped increase monthly domestic production of N95 masks from 20 million to 150 million and ventilators from less than 3,000 to more than 40,000 (GAO, 2020). But, as persistent shortages underscore, these efforts were too late and too few. Biomedical Advanced Research and Development Agency (BARDA) looked far enough ahead in May 2020 to invest more than $300 million dollars with Corning, Inc., to expand U.S. production of borosilicate glass for vaccine packaging, but failed to anticipate the shortage of an essential component, mined sand, further up the supply chain. BARDA's failures to adequately plan and respond were hamstrung, according to recent reporting, in part because so much of its resources were devoted to anthrax vaccines, which had limited public health value, but powerful political benefactors (Hamby & Stolberg, 2021).

There was also welcome, but long overdue, action by the Centers for Medicare & Medicaid Services (CMS) to track inventory held by hospitals. In October 2020, pursuant to authority provided under the federal Public Health Emergency declaration, CMS finally required weekly reporting of PPE supplies as a condition of ongoing Medicare reimbursement (42 CFR § 482.42(e) and 485.6). (See Table 24.1.) The overall strategy continued to suffer from poor coordination. A November 2020 Government Accountability Office (GAO) report found a pressing need to "develop and communicate to stakeholders plans outlining specific actions the federal government will take to help mitigate remaining medical supply gaps necessary to respond to the remainder of the pandemic" (GAO, 2020).

The Trump administration left office having sent to the SNS fewer than half the 300 million N95 masks it had promised in May. Health care workers and government agencies continue to report inadequate stock of masks, gloves, gowns, and other essential PPE (FDA, 2021). Other basic medical supplies — like testing components and oxygen — have run dangerously low this winter. Scarcity has shifted in predictable directions. Requests to Get Us PPE were evenly split between hospitals and other entities in the spring, but by fall, 90% of requests were from homeless shelters, humanitarian groups, and schools. Concerns about vaccine-related shortages (syringes, for example) have also emerged.

The Problems

Despite supply chain disruptions and unprecedented demand, concerted federal action could have replenished most basic supplies in the United States over the last year. While initial problems are fairly attributable to long-term disinvestment in public health infrastructure (Anderson & Burris, 2020), blame for ongoing shortages falls squarely on the Trump administration's unwillingness to mount a serious response. Fixing the problem is a priority for the incoming administration, which views assuring the supply of essential medical tools and medicines as the lynchpin of an effective and equitable pandemic control policy. Unfortunately, the time to prevent shortfalls happening in winter 2021 was in the spring 2020, because even aggressive and immediate

Table 24.1. Select PPE-related fields that must or may be submitted every Wednesday to maintain participation in CMS pursuant to current interpretive guidance (CMS-3401-IFC)

FIELD #	INFORMATION NEEDED
27	**On hand supply (DURATION IN DAYS)** a) Ventilator supplies b) N95 respirators c) Surgical and procedure masks d) Eye protection including face shields and goggles e) Single-use gowns f) Exam gloves (sterile and non-sterile)
28	**On hand supply (DURATION IN DAYS)** a) Ventilator supplies b) N95 respirators c) Surgical and procedure masks d) Eye protection including face shields and goggles e) Single-use gowns f) Exam gloves (sterile and non-sterile)
29	**Are you able to obtain these items? (Y/N/NA)** a) Ventilator supplies (any supplies excluding medications) b) Ventilator medications c) N95 respirators d) Other respirators such as PAPRs or elastomerics e) Surgical and procedure masks f) Eye protection including face shields and goggles g) Single-use gowns h) Exam gloves i) Are you able to maintain a supply of launderable gowns?
30	**Are you able to maintain at least a 3-day supply of these items? (Y/N/NA)** a) Ventilator supplies (any supplies excluding medications) b) Ventilator medications c) N95 respirators d) Other respirators such as PAPRs or elastomerics e) Surgical and procedure masks f) Eye protection including face shields and goggles g) Single-use gowns h) Exam Gloves i) Laboratory – nasal pharyngeal swabs j) Laboratory – nasal swabs k) Laboratory – viral transport media
31	**Does your facility re-use or extend the use of PPE?** a) Reusable/launderable isolation gowns b) PAPRs or elastomerics c) N95 respirators

Source: Interim Final Rule (IFC), CMS-3401-IFC; Requirements and Enforcement Process for Reporting of COVID-19 Data Elements for Hospitals and Critical Access Hospitals, October 6, 2020.

countermeasures will take months to bear fruit. The Biden team will have to manage scarcity for multiple supplies in the short term while efforts to boost production take hold.

Inadequate supply of PPE and other supplies has its roots in multiple factors. Health care is delivered as a business in the United States, which leads to "just-in-time-purchasing" to trim costs, reducing slack in reserves. Zealous cost-cutting also cripples domestic production. Even as U.S. firms were heeding the call to scale up domestic PPE production this summer, health entities turned back to cheaper foreign suppliers. The CEO of the National Council of Textile Organizations lamented in August about an "industry that's working only at 10-20% capacity, who can make PPE in our own backyard, but have no orders" (Glenza, 2020).

Global market conditions are also important. Competitive disadvantages — higher wagers, more regulations, less state support — hamper U.S. producers of low-margin goods like masks and gloves. It is telling that the largest supplier of PPE to U.S. states early in the pandemic, which fulfilled more than a $1 billion in orders, was a Chinese automotive company that had not sold one mask before the pandemic. Part of the reason that company could afford to pivot so aggressively was that the Chinese government protected it from downside risk. In contrast, U.S. companies expanding to meet surge demand in recent years ended up with unused stock and excess production capacity when the crisis passed and buyers went back to cheaper suppliers abroad (Martineau, 2020). Leaving states, individual health systems, and providers to fend for themselves pushes them into a maelstrom of foreign producers and intermediaries. Verifying that these businesses are legitimate and that supplies comply with U.S. regulations has been vexing.

As the focus turns to more complex products, like medicines and vaccines, technical issues also come into play. Medicines and vaccines are typically difficult to manufacture. The process of pharmaceutical production at scale is unforgiving of even the slightest deviations in conditions or contamination (remember those CDC testing kits?). Global manufacturing capacity is limited and requires time to expand. Shifting production lines from other vaccines to COVID-19 vaccine merely shifts the health risk. There are legal mechanisms for governments to force patent holders to license production to willing manufacturers, or even march in and take over production lines, but aside from the political barriers to doing so in the United States, we have yet to see evidence that manufacturers are not doing the best they can.

The Legal Path Forward

In its earliest days, the Biden administration can use its legal authority to take two immediate steps. First, it should use its power under Title III of the DPA to issue large, long-term purchase commitments to domestic producers of masks, gloves, gowns, and other essential supplies. This will incentivize firms to expand production lines and set the country on a course to restock the SNS. Second, the federal government needs to increase transparency and situational awareness in our health agencies. To this end, it should maintain reporting requirements for hospitals adopted by CMS under emergency powers (see above) and extend those requirements to other settings like schools, prisons, and nursing homes through the relevant federal agencies. The new administration can also deploy the subpoena power in the DPA to compel production and market information from entities that do not fall under the purview of emergency rulemaking authority. It may be particularly important to make sure that government regulators and purchasers have as clear a view as possible of vaccine production capacity and performance.

These important stopgap measures can stimulate production and guide allocation over the next year. Ultimately, however, prevailing market conditions — in terms of the drivers of demand and supply, and the price elasticity for purchasers — will concentrate some essential supply chains back offshore. There are plenty of legal levers to alter those dynamics. Changing procurement requirements, like extending the Berry Amendment (which requires uniforms and other textiles for the Defense Department to be produced by U.S. firms) to the Department of Health and Human Services (HHS) procurement of essential medical supplies, might stabilize business planning for domestic manufacturers. But, the practical effects of even such minor market interventions are complex and unpredictable. Legal intervention is complicated by the fact that supply chain dynamics differ across different products, industries, and distribution channels, and any product is just one element in a manufacturing economy that is globalized across virtually all products and sectors (Gereffi, 2020). The United States may want to be more protective of strategic products, but as the second largest exporter of medical goods, the U.S. medical supply industrial base also has much to lose from an erosion of free trade.

To sustain a nimble management response in a complex market, the federal government needs to perform advanced planning, monitor domestic production capacity and global supply chains, analyze markets to assess the global availability of PPE and ventilator components, and create sourcing plans for every key need that might arise. To do this kind of planning, it needs to rebuild a qualified staff and ensure reliable and real-time data about inventory. We suggest this capacity be part of the SNS. Changing the culture and technical infrastructure of the SNS will take time and money; the SNS's inventory-management systems have not been upgraded since 2004. One group of researchers observed SNS staffers photographing pallets with their cell phones as a method for inventory reporting. It may be best to re-envision SNS as a virtual "control tower" capable of monitoring, housing and allocating supplies (Handfield et al., 2020). It is imperative to align SNS spending with credible science about the documented benefits of different countermeasures, and not with the financial interests of a few firms with the best lobbyists (Hamby & Stolberg, 2021).

As we described in Volume I, the problem of medical supply shortages in emergencies is not directly caused by law, and the legal power already exists to enable strong federal action to prevent and contain shortages. Yet when we step back and consider the place of the health care industry in the roots of the problem, and the functional neglect of the safety of millions of mostly female, disproportionately non-white health care and essential service workforce, the need for proactive legal change looms large.

Our labor and occupational safety and health laws are failing the people who process, prepare, and retail the food we eat, who provide basic care and sanitation in hospitals and nursing homes, and who operate public transit. As detailed in other Chapters of this Assessment, chronic low pay, lack of collective bargaining, and lax safety regulation have exposed people to unnecessary COVID-19 exposure. In a regulatory environment where workers are legally protected and empowered, we could expect much stronger provision of PPE in the business plans of health care institutions and other essential operations, and stronger signals to the federal government on the importance of properly planning and performing. Equity and health equity depend on legal changes that go far beyond improvements in the SNS or better use of the DPA. COVID-19 has highlighted the way low wages, lack of paid sick leave, crowded housing, truncated worker's rights, and the under-funding of occupational safety and health agencies put workers at risk of infection (and many other ills) and drive racial health inequities. Better working conditions, more affordable healthy housing, and higher pay require legal action now.

Conclusion

The DPA provides a flexible set of powers that enables the executive branch to assume responsibility to plan, instigate and strategically coordinate public-private collaboration as part of a national program to assure necessary health supplies to every state. The federal government can still bring to bear its human and economic resources to identify shortages and nudge suppliers to ramp up production with investment and purchase orders; it can coordinate the purchase and distribution of existing supplies to get material where it is most needed. Long-term purchasing and investment deals will ultimately yield a surplus of basic supplies that can be used to rebuild a truly adequate SNS.

These immediate steps must not be the end of the story of national emergency infrastructure failure. PPE presents yet another instance of the double benefits of pro-equity policies. Addressing the underlying labor market and employment law inequities that have made contributed to disparities in PPE access and COVID-19 infection will make our country fairer for those who have suffered injustice. But it will also reduce the future vulnerability of the whole country to pandemics.

Recommendations for Action

Federal government:

- The president should empower and equip with the necessary resources competent career government staff to use federal emergency and DPA authority;
  - Identify and assess the availability of all basic medical equipment required for COVID-19 response;
  - Assess domestic and international production capacity and supply chains;
  - Use investment and purchasing to incentivize manufacturers to add necessary capacity;
  - Develop and implement a strategy for federal procurement and need-based distribution to states.
- Congress and the White House should jointly convene an independent commission of inquiry to conduct a thorough public investigation of the federal and state government preparation for and response to COVID-19.
- Congress should reaffirm the role of the SNS as the primary resource for the nation during emergency surges in demand, and institute a long-term funding plan for assuring supplies commensurate with predicted need.
- Congress should fund and HHS should properly implement and manage the long-term staff and infrastructure to monitor, track, and use the resources of BARDA to proactively address deficiencies in the supply chain for essential medical equipment.
- HHS should develop, with real attention, new regulations on emergency supply chain management including developing and implementing "stress tests" for supply chains for key products, and reorganize accordingly

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Allocating Medical Resources during Times of Scarcity

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SUMMARY. Scarcity of medical resources and services during public health emergencies raises challenging legal and ethical questions. The COVID-19 pandemic has strained the capacity of health systems, and revealed some of the shortcomings of previous efforts to plan for and implement ethical and effective allocation protocols for scarce medical resources and services. Governments and health institutions have ample authority and expertise, but often lack the political and economic support needed to avoid shortages and mitigate their severity. Legal issues that may arise in this context include liability for health care professionals and institutions that must make allocation decisions when resources are scarce and civil rights concerns over discrimination in crisis standards of care protocols or their implementation. In the short term, federal and state officials must expand available resources to mitigate resource scarcity in the COVID-19 response. They must provide legal and practical guidance to health care and public health entities that may need to implement crisis standards of care, and ensure that scarce resources — including newly-developed treatments and vaccines — are allocated consistent with legal and ethical responsibilities that protect the most vulnerable persons through fair and equitable prioritization. In the longer term, federal and state officials should support efforts to clarify and incorporate protections into crisis standards of care plans that prioritize antidiscrimination, fairness, and equity in allocation decision making.

Introduction

This Chapter addresses how legal and ethical considerations apply to situations of scarcity that may arise during the response to the COVID-19 pandemic and similar public health emergencies. Throughout the COVID-19 pandemic, health care facilities, EMS providers, public health departments, and long-term care facilities in the most-affected areas have had to consider adapting their patient care practices to account for potential shortages in medical resources and services. Severe shortages can result in the need to make challenging and tragic triage decisions, as health professionals are forced to determine who gets a scarce medical resource or service when there is not enough for everyone who needs it.

Chapter 24 in Volume I, Assessing Allocation of Scarce Resources and Crisis Standards of Care, examined the conditions under which pandemics can give rise to scarcity of medical resources and services, and the infrastructure in place to deal with resource allocation decisions under conditions of scarcity, including crisis standards of care guidance. That Chapter also analyzed the corresponding legal challenges that may arise under theories of civil liability or civil rights violations (Gable, 2020).

In the intervening seven months, concerns about medical resource shortages have become even more acute as the winter 2020-2021 wave of COVID-19 patients has stretched health care facilities to — and in some cases beyond — capacity. Despite the increased availability of COVID-19 testing and some supplies (like mechanical ventilators) compared with the spring 2020 COVID-19 patient surge, many U.S. health care providers have continued to experience shortages of medications, personal protective equipment (PPE), and most importantly, qualified staff to treat the influx of new patients. Mirroring conditions seen in Wuhan, China; Lombardy, Italy; and in New York City early in the pandemic, areas like Los Angeles experienced substantial surges in COVID-19 cases and hospitalizations in December 2020 and January 2021. In the absence of strong federal government leadership, national organizations urged state and local governments and private sector health leaders to take immediate action to implement crisis standards of care while ensuring equitable resource allocation (NAM, 2020).

The re-emergence of medical resource and service shortages affirms that many of the lessons that should have been learned early in the COVID-19 pandemic to avoid scarcity have not been heeded. This Chapter recommends a series of legal and policy proposals that will help avoid scarcity of medical resources and services, and ensure that when crisis standards of care must be implemented, such implementation occurs consistent with principles of equity.

Resource Scarcity and Allocation

Avoiding Scarcity

Ethicists and policymakers agree that preemptively avoiding scarcity of medical resources and services is a fundamental obligation of leaders in government and the private sector. These leaders also have an essential duty to plan for implementation of surge capacity and the development of effective and equitable scarce resource allocation protocols in settings where health services are provided, including health care and public health settings (Hick et al., 2020,). Furthermore, since scarcity of medical resources and services and allocation protocols tend to exacerbate health disparities that disproportionately disadvantage people of color, people with disabilities, and other politically- and socially-marginalized populations, taking preemptive measures to avoid scarcity and to plan for equitable allocation protocols also advances equity in public health emergency responses.

The Volume I analysis of scarce resource allocation posited several factors contributing to scarcity during the COVID-19 pandemic. Inadequate planning and investment in surge capacity by governments and health care facilities prior to the pandemic undermined systemic resilience. Slow or insufficient reaction to the novel public health risks posed by COVID-19 allowed the case rate to grow to an unmanageable level. Government leaders failed to coordinate distribution, sharing, and use of necessary resources to facilities and patients in need. The cost-centric, redundancy-averse, for-profit health care system in the United States creates (and continues to perpetuate) underlying economic incentives and systemic shortcomings that render public health preparedness more difficult and less equitable (Gable, 2020).

As time passed and the second wave of supply and personnel shortages occurred, it became clear that many of these factors continue to undermine efforts to avoid shortages. Due to the efforts of the federal government and some state governments to downplay the seriousness of the COVID-19 outbreak, government entities and private institutions had fewer incentives and less support for expanding stockpiles of supplies and developing plans for crisis standards of care. While some regions took greater precautions after experiencing the narrow avoidance of overwhelmed hospitals in spring 2020, others paid insufficient heed to these experiences in their own areas. Further, while many hospitals had suspended non-essential procedures during the spring 2020 surge to conserve resources, most health care entities attempted to continue non-essential procedures during the winter 2020 surge, driven by both public health and economic goals.

Analyses of the early response efforts in New York City also highlighted that the existing crisis standards of care plans were insufficient to deal with the clinical decisions that arose in many health care facilities. Staff shortages were the most obvious and persistent challenge faced by many hospitals and health care facilities, yet most of the existing plans focused more on supply shortages. Further, most crisis standards of care plans focused on worst-case scenarios, such as removing a patient from a ventilator to re-allocate it, rather than more likely circumstances such as how to stretch scarce personnel and PPE over many months (Toner et al., 2020). Indeed, the most challenging supply shortages during the winter 2020 surge were staff shortages. Overwhelmed hospitals in New York City were able to function during April and May 2020 due to an influx of trained health professionals from other parts of the country to supplement staffing shortages, but the nationwide spike in COVID-19 cases in December 2020 rendered similar personnel sharing impossible as all areas of the country experienced COVID-19 outbreaks simultaneously.

The most direct tools that can avert potential scarcity of medical supplies remain in the hands of the federal government. Congressional appropriations can directly support creating reserves of supplies likely to be needed in public health emergency responses and can incentivize the development of crisis standards of care planning. The Defense Production Act has the potential to be used to expand manufacturing capacity for needed supplies. Yet, the Trump administration used this authority sparingly and allowed resource shortages to persist. The Strategic National Stockpile (SNS) distributed supplies — including N95 respirators, face masks, face shields, gowns, gloves, and ventilators — to state and local jurisdictions early in the pandemic. However, the SNS cannot assist overwhelmed facilities with personnel shortages.

Implementation of Crisis Standards of Care and Liability Protections for Allocation Decisions

The concept of crisis standards of care has been widely adopted by emergency planners to apply to situations where "a substantial change in usual health care operations and the level of care it is possible to deliver" occurs (IOM, 2009). During the COVID-19 pandemic, many states have developed or updated non-binding guidance for implementing crisis standards of care, adopting a variety of standards and approaches (Manchanda et al., 2020). Importantly, however, few states have formally invoked legal provisions (statutory, regulatory, or executive orders) that would explicitly authorize an alteration in the standard of care to address resource shortages in health care or related settings. The Arizona Department of Health Services formally designated that state crisis standards of care were in effect in June 2020, allowing hospitals to implement triage protocols if necessary. New Mexico's governor issued an executive order in December 2020 activating state crisis care standards, and relaxing state licensure and credentialing guidelines for health care professionals. Virginia also authorized health care providers to declare a crisis standard of care to execute triage protocols or scarce resource allocation policies in April 2020. California's surge in cases in January 2021 did not result in a formal statewide order altering standards of care, but the California Department of Public Health required hospitals to publicize their scarce resource allocation plans and prepare to implement crisis standards of care. EMS providers in Los Angeles were instructed to conserve oxygen and to not transport adult patients to hospitals if they could not be resuscitated at the scene of the emergency (Evans & Mai-Duc, 2020).

Despite these state and local orders, there have been no explicitly documented cases in any of these jurisdictions of health care facilities formally implementing crisis standards of care protocols and making triage decisions based on them. By contrast, there

is ample anecdotal evidence of hospitals and EMS agencies in numerous locations taking informal, adaptive steps to stretch health care capacity to deal with COVID-19 patient surges, effectively changing the standard of care that patients receive (Toner et al., 2020; Evans et al., 2020).

The potential for tort liability related to resource allocation decisions looms over many discussions of crisis standards of care. The professional standard of care applicable to medical, nursing, or EMS treatment adapts with the circumstances, so a professional working under situations of scarcity need only provide the care that would be expected under those circumstances of scarcity to avoid liability in most cases. The legal position of the health provider will be even stronger if government officials have declared an emergency or disaster, or government officials or even private entities have recognized that a contingency or crisis standard of care is in effect.

Many health care professionals support more explicit liability shields to provide immunity for allocation decisions. States have taken steps to protect health care professionals — and in some cases health care and long-term care facilities — from liability for triage and scarce resource allocation decisions during declared emergencies. Maryland and Virginia, for example, both extend immunity from civil liability to health care providers who make good faith triage decisions due to medical resource scarcity during a declared emergency, with Maryland also granting immunity from criminal liability (Maryland Code, Public Safety, sec. 14-3A-06; Virginia Code, secs. 8.01-225.01, 8.01-225.02). At least 24 states have adopted COVID-19-specific liability shields for health care professionals by executive order or legislation, which would presumably cover resource allocation determinations related to COVID-19 care (see Chapter 31).

Ensuring Equity in Scarce Resource Allocation

The COVID-19 pandemic has exacerbated health disparities. Communities that primarily consist of Black people, Indigenous people, other people of color, older people, and people with disabilities have faced higher rates of illness and death related to COVID-19. The health disparities that produce higher rates of morbidity and mortality in these communities — both generally and specific to COVID-19 — can perniciously reduce the priority of patients from these communities to access scarce resources, since many scarce resource allocation plans favor patients with the highest likelihood of successful medical treatment (Shaw, 2020). While these plans appropriately place great ethical and practical importance on mitigating the spread and harm of COVID-19 through saving the most lives, protocols for allocating scarce resources also must maintain fair and equitable distribution of scarce resources. Maximizing lives saved and prioritizing equitable allocation may appear to be in tension in some situations, but an ethical public health response can, and must, balance both factors.

Equity can be better achieved during times of medical resources scarcity through the application of two strategies. First, scarce resource allocation protocols must explicitly recognize and incorporate equity as a fundamental goal of such protocols. Second, civil rights and anti-discrimination laws must be enforced to ensure that patients receive the best possible care even when resources are limited, while simultaneously protecting against discrimination and disparate treatment of individuals from historically-marginalized communities.

Centering Equity in Crisis Standards of Care Plans

While allocation protocols in crisis standards of care plans vary from state to state, most of these plans base allocation decisions in significant part on an individual patient's medical prognosis. At least 10 states' plans apply criteria to categorically exclude people from accessing critical care resources such as ventilators, while many more states consider factors such as long-term comorbidities and algorithms, such as the Modified Sequential Organ Failure Assessment to determine priority to resources (Manchanda et al., 2020). Exclusion criteria often explicitly disfavor access to scarce resources for people with physical or intellectual disabilities, and have been legally challenged (see discussion below).

Most states also prohibit prioritization of access to scarce resources based on demographic factors (such as race, ethnicity, age, etc.) and factors related to social standing. While this type of facially neutral framework seems ethically appealing and can be important to prevent overt discrimination, it also can allow inequity to persist in resource allocation decisions since age and disability status, for example, can affect clinical assessments of medical prognosis, long-term survivability, and quality of life (Bagenstos, 2020). Officials in state government and leaders in private entities tasked with implementing crisis standards of care should counteract explicit and implicit structural inequities built into medical resource allocation plans by eliminating rigid exclusion criteria; incorporating tools to reduce disparities in allocation decisions such as the CDC's Social Vulnerability Index; and pursuing public input and engagement in the development of crisis standards of care protocols, including representation from communities that are most effected by the consequences of COVID-19 infections and most likely to be disadvantaged by crisis standards of care protocols.

Civil Rights Protections and Crisis Standards Of Care

Federal civil rights and antidiscrimination laws provide another avenue to achieve more equitable results in scarce resource allocation decisions in health care settings. For example, the Rehabilitation Act of 1974, Title II of the Americans with Disabilities Act, and Section 1557 of the Affordable Care Act, provide protection people for people with disabilities from discrimination in health care settings. The U.S. Department of Health and Human Services Office for Civil Rights (OCR), which enforces these laws, has acted aggressively over the past year to resolve legal challenges to crisis standards of care policies from disability rights advocates (Mello et al., 2020). OCR has resolved complaints against Alabama, North Carolina, Pennsylvania, Tennessee, and Utah, and the North Texas Mass Critical Care Guidelines Task Force, the Southwest Texas Regional Advisory Council, and the Indian Health Service to remove categorical exclusions and discriminatory policies within crisis standards of care plans.

In January 2021, OCR issued technical assistance addressing age and disability in crisis standards of care plans. This guidance prohibits categorical exclusion criteria, as well as the use of criteria that account for a patient's long-term life expectancy or the resource-intensity and duration of need. The guidance also suggests modifications to ensure clinical instruments accurately assess the likelihood of short-term survival for people with disabilities. It includes protections against pressuring patients into agreeing to withdrawal or withhold life-sustaining treatments or use of blanket do not resuscitate orders, and prohibitions on reallocation of personal ventilators brought by a patient to an acute care facility to continue pre-existing personal use.

The Biden administration has stated that it will provide guidance and strengthen enforcement to ensure that crisis standards of care policies do not discriminate. These steps are important to ensure that equity in resource allocation is achieved. Likewise, states should review their crisis standards of care plans to clarify necessary protections under federal and state antidiscrimination law.

Allocation of COVID-19 Vaccines

One of the most prominent examples of the legal and ethical challenges created by resource scarcity involves the distribution and allocation of COVID-19 vaccines. In anticipation of COVID-19 vaccine approvals, the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) and an ad hoc committee of the National Academies of Sciences, Engineering, and Medicine (NASEM) developed recommendations for equitable vaccine distribution. These allocation proposals seek to maximize public health benefits and minimize harm, uphold human dignity, and promote justice, while simultaneously mitigating health inequities (Dooling et al., 2021; National Academies, 2020). At the time of this writing, the Pfizer, Moderna, and Johnson & Johnson COVID-19 vaccines have been approved through FDA Emergency Use Authorization, but are only available in limited supply. While changes in manufacturing capacity and the approval of additional COVID-19 vaccines may expand access in the near future, shortages of vaccines are likely through at least summer 2021 and possibly longer in the United States. Worldwide, shortages are likely to last much longer. Thus, allocation protocols and their successful implementation are essential to target vaccinations where they will have the most public health benefit and can mitigate health inequities.

The ACIP and NASEM guidance have been influential, but actual allocation protocols are being determined and administered at the state and local levels, with varying levels of success. Most states have used private entities such as hospital systems and pharmacies to act as intermediaries to provide vaccinations to the first identified priority groups: front-line health care workers and long-term care facility residents and staff. Many states quickly expanded eligibility for vaccines beyond these groups, allowing other essential workers and adults older than age 75 — or in some states older than age 65 — to receive COVID-19 vaccines. These categories of people are so large and heterogeneous that disparities exist even with groups, so prioritization of these large categories alone will be insufficient to avoid disparities within priority groups (Artiga & Kates, 2020).

Early evidence suggests that the same disparities in access to health care resources that exist already in the United States are being perpetuated in the COVID-19 vaccine rollout, with members of racial and ethnic minority groups facing more obstacles to obtaining COVID-19 vaccinations than members of wealthy white communities, despite explicit plans to avoid such disparities (Goodnough & Hoffman, 2021). Structural and practical strategies — including more targeted vaccine distribution and allocation protocols and expansion of access options in more vulnerable communities — must be employed to combat these emerging disparities. Additionally, targeting limited vaccine supplies to communities most in need using tools such as the Social Vulnerability Index or Area Deprivation Index could reduce disparities in access (Schmidt et al. 2020).

The initial challenges in implementing equitable vaccine allocation processes demonstrate that having well-designed, ethically thoughtful plans is not enough to achieve equitable results. Federal, state, and local official must take steps to affirmatively connect vulnerable populations with available vaccines through more deliberate outreach. The Biden administration's National Strategy for COVID-19 Response seeks a more coordinated, expansive, and well-funded vaccine distribution effort, with a focus on equity and reaching hard-to-reach populations. These efforts are key to saving lives and hastening the end of this pandemic. Successful and equitable administration of COVID-19 vaccines not only hastens the end of the pandemic through herd immunity but also greatly reduces the number of serious COVID-19 infections, which makes resource shortages and crisis standards of care much less likely to occur. Going forward, continuing to plan for and alleviate scarcity, and building a robust public health infrastructure can render the terrible possibility of triage exceedingly rare.

Recommendations for Action

Federal government:

- Congress should increase and maintain funding for public health emergency preparedness through a dedicated public health emergency fund; should expand support for the National Hospital Preparedness Program, the Strategic National Stockpile, and vaccine manufacturing capacity; and should fund state, local, and private sector efforts to expand COVID-19 vaccination capacity.
- OCR should develop, expand, and update best practices and guidance for the allocation of scarce resources and crisis standards of care consistent with federal antidiscrimination laws.

State governments:

- State legislatures or executive agencies should develop and approve protocols for crisis standards of care, and allocation of scarce medical resources and services during declared emergencies, disasters, or public health emergencies.
- State legislatures or executive agencies should develop clear indicators and triggers for when crisis standards of care apply, including guidance for the distribution of new treatments and vaccines for COVID-19 that center both efficacy and equity.
- State legislatures or executive agencies should pursue public input and engagement in the development of crisis standards of care protocols, including representation from communities that are most affected by the consequences of COVID-19 infections and most likely to be disadvantaged by crisis standards of care protocols.
- State legislatures should enact statutory provisions outlining the process for imposing crisis standards of care to establish a clear process for when crisis standards of care are in place, who has the authority to impose altered standards of care, and the limitations of such authority.
- State legislatures should review their crisis standards of care protocols to clarify necessary protections under federal and state antidiscrimination laws.

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The author would like to thank Allison Tuohy for research assistance.

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PART 5

Protecting Workers and Families

Meeting the Needs of Vulnerable and At-Risk School-Age Children

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SUMMARY. In March 2020, in response to concerns about the rapidly spreading coronavirus, schools across the nation closed to in-person instruction. Despite having laws and policies addressing education in a public health emergency, school districts lacked comprehensive plans addressing specific issues raised by COVID-19. The outbreak has exposed a lack of preparation for providing education and services, and inability to adapt instruction in an extended emergency, which has further exacerbated existing education and health inequities. Many students, particularly minorities and students from low-income families, did not have access to the internet or the technology required to participate in online instruction. English-language learners and students with special needs for whom in-person school is critical also struggled in this new learning environment. Education is a significant social determinant of health, linked to long-term health outcomes of infant mortality, health behaviors, and even life span. Schools also play an important role in short-term health of students, including nutrition, physical health and activity, and mental health and well-being. Federal, state, and local governments and school districts must work together to devise and implement trauma-informed, equity-centered education strategies.

Introduction

The outbreak of COVID-19 has caused unprecedented disruption to the education of children in the United States, the impact of which is likely to result in significant long-term health effects and widen already existing health disparities faced by minority, low-income, and otherwise disadvantaged communities.

Evidence suggests that children under the age of 21 experience milder COVID-19 symptoms (Bixler et al., 2020). However, children may contract the disease, be asymptomatic and transmit the disease to other family or community members. To reduce disease spread, schools across the country have been closed to in-person learning in varying degrees since mid-March 2020, potentially slowing academic progress and even causing regression. Many children lack technology, broadband internet access, and parental assistance to participate in school activities and support learning.

Disruption in education has severe consequences because education "is the most important modifiable social determinant of health" (Lancet, 2020). While necessary to reduce the spread of coronavirus, emergency school closures and subsequent remote schooling have affected students' health in a myriad of ways as well. These include reduced daily exercise; lack of consistent access to healthy meals; disconnection from peers, stress from family circumstances, grief, and other mental health concerns; decreased and less effective delivery of special education services, including nursing and speech, occupational, and physical therapies; lack of safe supervision for children of low-paid essential workers; and reduced reporting of child maltreatment. Further, some schools provide direct physical and mental health services through school nurses and counselors, school-based health centers, or partnerships with community organizations, and have had to alter or discontinue service provision.

Although all children are negatively affected by disruption of in-person instruction, students from low-income communities, students with disabilities, students identifying as LGBTQ, students involved with the child welfare system, students experiencing homelessness or parental unemployment, or students for whom English is not their family's primary language may face even greater challenges. While some view education as "the great equalizer," the impact of COVID-19 has exposed and widened many existing educational and health disparities. Guidance from the Centers for Disease Control and Prevention updated on February 11, 2021, recommends strategies for reopening schools to in-person learning while reducing risk of disease spread including handwashing; universal and correct mask wearing; social distancing; cleaning and maintaining health facilities; and collaborating with the health department with isolation, quarantine and contact tracing. However, schools continue to grapple with the very real challenge of balancing the benefits of in-person learning with the costs and other barriers to preventing COVID-19.

Federal, State and Local Authority for Education

In the United States, there are approximately 50.8 million school-age students enrolled in nearly 100,000 public schools in pre-kindergarten through 12th grade (Wilkinson-Flicker, 2019). State governments have primary authority for public education, with the federal government having a limited role. Governance of schools varies by state with states delegating differing degrees of authority to the more than 13,500 local education agencies (LEAs) across the country. Pre-pandemic annual spending on education for kindergarten through 12th grade is estimated at $680 billion, an average of $13,440 per student (Wilkinson-Flicker, 2019). The majority of funding for education is split between state and local governments, with the federal government only contributing approximately 8% (Hussar et al., 2020). In a public health emergency, like the COVID-19 pandemic, LEAs look to state and federal leadership for direction as well as additional funding.

Many state departments of education had public health emergency response plans in place that addressed issues such as reporting student cases to local health officials, authorizing school exclusion and re-admittance of students, and authorizing school closures. Lacking, though, were comprehensive policies addressing many of the issues arising with COVID-19, such as preventing disease spread, remote instruction, and access to services during school closures (Nuñez et al., 2020). Districts clamored to develop policies as the outbreak unfolded and continue to face challenges.

Funding to Address the Pandemic

In March 2020, recognizing schools would be faced with significant unforeseen expenses to address the pandemic, Congress provided states $13.5 billion in the Education Stabilization Fund included in the Coronavirus Aid, Relief, and Economic Security (CARES) Act of 2020. States were required to distribute 90% to school districts based on population-based funding formulas in Title 1 of the Elementary and Secondary Education Act (ESEA). States could use the remaining 10% to respond to COVID-19-related emergency needs. Congress also earmarked $3 billion for governors' discretion for child care through college and authorized flexibility to combine and carry over certain funding streams.

States quickly discovered that the CARES Act did not fully address the extensive needs of the education system. In late December, Congress approved an additional $54.3 billion for public elementary and secondary schools through the Consolidated Appropriations Act of 2021. States again may retain 10%, $1.3 billion is included for governors' discretion for public schools, and an additional a $2.7 billion is allocated specifically for private schools.

States and LEAs have flexible use of relief funds. Funds may be used to expressly prevent spread of the virus, such as purchasing personal protective equipment (PPE) and supplies, increasing staff to sanitize schools, or upgrading ventilation systems. Funds may be used to prevent loss of learning through assessments, materials and technology. Funds may also address students' mental health needs. Additionally, funds may be used to mitigate disparate impact of the disease, focusing on the needs of disadvantaged students, low-income students or students experiencing homelessness, students with disabilities, or non-native English speakers. Finally funds may be used to improve administrative coordination, staff training, and developing and improving preparedness and response plans for addressing public health emergencies.

Vulnerable and At-Risk Students

Race and Income

Race and income are intricately intertwined, and racial and economic inequities have further complicated the response to the pandemic. Minority and low-income communities have been disparately affected by COVID-19. Data demonstrates disproportionately higher rates of COVID-19 deaths and hospitalizations among racial and ethnic minorities younger than 21 years old (Bixler et al., 2020).

Prior to the pandemic, student achievement at predominantly white schools was greater than predominantly Black schools. A greater proportion of minority students attend high-poverty schools, which have greater achievement gaps than more affluent schools. High-poverty schools are more likely to have younger, less experienced teachers and higher teacher turnover rates. Schools with fewer resources are unable to provide as many academic options, such as advanced courses. Families in these communities may have less access to quality early childhood opportunities to prepare children for school, internet service, and computers. Further, parents in these communities have less political, social, or economic capital to effect school improvements (Reardon et al., 2019).

Educational disruption due to COVID-19 has exacerbated existing disparities, and the full impact may not be known for years. As COVID-19 began to spread in the spring of 2020, schools across the country shut down and reopened with varying degrees of online teaching in the fall: 24% reported providing instruction fully online, 51% hybrid in-person/online instruction, and 17% offering instruction fully in person, with some allowing parents to choose online instruction (Honein et al., 2021). Only 60% to 70% of Black and Hispanic students are regularly participating in online learning. Compared to 90% of higher income students, only 60% of low-income students are regularly logging on (Dorn et al., 2020). This is even more troubling given that poor attendance is a strong predictor of non-completion (Chang et al., 2008).

Students' access to high-quality or even adequate online instruction differs, with some students receiving low-quality instruction or even none at all, potentially resulting in widening the achievement gap, slowing learning, or causing learning loss (Dorn et al., 2020). Not having a quiet environment or sharing devices among multiple students in the home are further obstacles to successful online learning. Families with parents working outside the home may be unable to provide assistance with schooling, and minorities are overrepresented among low-paid essential workers in health care, transportation, food services and groceries, utilities, and sanitation who are unable to work from home (Rogers et al., 2020).

Special Education Access

Nationwide, 14% of students receive special education services under the Individuals with Disabilities Education Act of 2004 (IDEA),

Section 504 of the Rehabilitation Act of 1973, and the Americans with Disabilities Act of 1990. Early in the pandemic, questions were raised about how to continue to implement special education services. The U.S. Department of Education (USDOE) initially released a statement on March 12, 2020, indicating that schools did not have to provide special education services if general education services were not provided. To avoid running afoul of the law, some states and LEAs opted not to offer any general education services, while other states and LEAs interpreted their remote offerings not as "education" but as supplemental learning opportunities or for enrichment only (Gavin, 2020).

While this approach may have made sense for a short-term closure, it quickly became obvious that response to the virus would last much longer than a few weeks. On March 21, 2020, the USDOE Office for Civil Rights, Office for Special Education and Rehabilitative Services recognized the problematic interpretation and released a fact sheet reversing the initial guidance, emphasizing that compliance with disability laws should not prevent offering distance learning.

Parents and advocates urged against alterations that might threaten services, while organizations supporting school administrators argued for flexibility in deadlines, processes, and paperwork. However, USDOE guidance from September 28, 2020, reiterated that IDEA provisions were not waived and students remain entitled to a free and appropriate public education (FAPE). Schools physically closed to prevent the spread of COVID-19 must consider alternative delivery options, such as online, by telephone, or in another location, like the student's home, if services can be provided safely. The USDOE did extend timelines for initial or re-evaluations considered invalid unless conducted in person. Student observations necessary for evaluation can be conducted by video with parental consent. The USDOE also allows for virtual individualized education program (IEP) meetings if the parent agrees. Schools are allowed, but not required, to create distance learning plans for students detailing how their IEP will be carried out until in-person instruction is again practicable.

While school districts remain obligated to provide special education services, many obstacles exist (Nowicki, 2020). Each student's IEP or 504 plan is, by design, individualized, making planning and service provision difficult. Ensuring the safety of staff and students has prevented services such as one-to-one aides, or speech, occupational or physical therapies in students' homes; however, for many students these services are difficult to provide remotely as well. Shortened synchronous instruction periods may not align with instructional hours committed in students' IEPs. Further, many students rely on the support of various adults throughout the day, requiring parents to assume many roles, from teacher to aide, to nurse, to service provider, sometimes while also assisting siblings or working themselves.

English Language Learners

English language learners (ELLs) make up 10% of students in the United States, and approximately three-quarters of ELL students' native language is Spanish (National Center for Education Statistics, 2020). More ELL students than English-speaking students live in poor households (Nowicki, 2020). USDOE guidance from May 18, 2020, states that if remote education is being provided, schools must continue to provide instruction to ELLs.

ELL students have disproportionately less access to technology and broadband, and ELL families may not understand how to use the technology to access online learning. Communication with ELL students and their families during COVID-19 has presented unique challenges too. Technical support, pandemic policies, and instructional materials are not always available in languages other than English or Spanish, and some online materials may not have captioning. In addition, remote learning limits opportunities for peer interaction to improve English language skills. These factors contribute to widening the achievement gap between ELLs and English speaking students (Nowicki, 2020).

Addressing Complex Problems

Technology Device and Internet Access

In the United States, 7.3 million children do not have access to a computer, laptop or tablet, and 16.9 million children lack home high-speed internet (Alliance for Excellent Education, 2020). This includes 31% of Black and Hispanic families and 34% of American Indian families, as compared to 21% of white families. The disparity is even greater for children living in low-income families: 4.6 million children who live in families that make less than $50,000/year do not have access to high-speed internet. Additionally, two out of five families in rural communities lack high-speed home internet. (Alliance for Excellent Education, 2020). Even more households express concern about being able to continue to afford home internet service, with COVID-related parental unemployment, illnesses, and even death.

Early in the pandemic, school districts scrambled to pivot from in-person to online instruction. Laptops and tablets were distributed to as many students as possible, though not all students received needed devices. Many internet service providers temporarily modified business practices to make wireless internet more accessible, sometimes even free. To help meet long-term needs, the Consolidated Appropriations Act provides a $3.2 billion Emergency Broadband Benefit Program, under which eligible low-income households can receive monthly discounts on broadband services. Eligible households may also qualify for laptop, tablet, or desktop computer subsidies.

Additionally, computer literacy is critical. Teachers must receive high-quality targeted training and support for teaching in an online environment. Students and parents may also need assistance with using the equipment to participate in class and complete assignments. For more on the digital divide, see Chapter 32.

Infrastructure

The lack of equal access to safe learning environments is a significant barrier to returning to in-person learning. While some schools in affluent and middle-class white neighborhoods with structurally sound buildings have been able to implement sufficient mitigation strategies to safely open schools to in-person learning,

schools in low-income minority neighborhoods have not, due to unequal building conditions of the school buildings. In fall 2020 almost twice as many districts in highly concentrated poverty areas were forced to provide remote-only learning than districts in lower poverty areas. More than 40% of school districts in the United States have outdated and poorly functioning ventilations systems in half of the schools within their districts (Harris et al., 2020). Because funding for school building infrastructure is a mostly local expense often tied to property taxes, it is not surprising that more schools in low-income communities are in need of repair. While the CARES Act and the Consolidated Appropriations Act allow for infrastructure improvements, the expense and time required for repair are significant.

Free or Reduced-Price Lunch Program

More than half of all U.S. students rely on the Free or Reduced-Price Lunch (FRPL) program for at least one daily meal. The Trust for America's Health states that "hunger, poor nutrition and food insecurity can increase a child's risk of developing a range of physical, mental, behavioral, emotional, and learning problems" (Trust for America's Health, 2020). Closure of schools to reduce the spread of coronavirus presented an immediate crisis for delivery of meals to children across the country. While LEAs made arrangements to serve students eligible for FRPL in their communities, initial confusion, delays in federal program approvals, difficulty with coordination with community stakeholders, and lack of family transportation to meal sites meant that some students may have missed meals.

The U.S. Department of Agriculture (USDA), which administers the program, has issued a number of waivers to facilitate school lunch service during the pandemic. Waivers provide needed flexibility for schools and families, such as allowing for delivery or pick-up of meals at different times, locations on or off-site, and with or without a child present. Recognizing that districts may have difficulty procuring certain foods, the USDA also waived certain nutrition requirements, although this could have negative consequences if scarce foods are replaced with less healthy and balanced alternatives. Some states have opted to provide meals for all children, regardless of FRPL eligibility. Some districts are providing multiple meals a day or multiple days' worth of meals a few times a week or weekly, thus reducing the contact between nutrition staff and families. Districts have also experimented with reaching families through different delivery models, such as using bus drivers to drive routes and make meal drops.

The Families First Coronavirus Response Act of 2020 authorized funds to be distributed through a Pandemic Electronic Benefits Transfer (P-EBT) program to students who would have received free or reduced lunches. Participating states can provide up to $5.70 per day to eligible students. The program was extended by the Continuing Appropriations Act of 2021.

Reporting of Child Abuse and Neglect

COVID-19 has exacerbated known risk factors for child maltreatment, including parental loss of employment, financial distress, and social isolation. Teachers and other school personnel are in the unique position to observe signs of child abuse and neglect, and, in most states, are mandated by state law to report reasonable suspicion of abuse or neglect. With school cancellation and remote learning, 40% to 60% fewer child abuse and neglect reports were made between March 2020 and May of 2020 than the same period in 2019, potentially leaving vulnerable children at risk (Weiner, et al., 2020).

An additional complication during the height of the pandemic was that, in some states, Child Protective Services was not investigating reports of maltreatment in person and instead conducting virtual visits. Virtual visits reduce caseworkers' ability to adequately assess circumstances of the child and family, substantiate allegations, or connect families to needed resources for stabilization.

Finally, children already in foster care are more vulnerable to school closures. Public schools serve as communities and provide children with important peer and adult connections for children in foster care who may not have consistent contact with their biological family. Thus, school connections may serve as a protective factor against further despair and isolation.

Recommendations for Action

Federal government:

- Congress should continue flexible funding designated for education-sector response to COVID-19 to reduce disease spread, prevent learning loss, and close achievement gaps. The Department of Education should also continue to allow for repurposing of existing funding streams.
- Congress should continue to fund and the Federal Communications Commission should continue to implement expansion of broadband to rural and low-income communities, providing access and affordability.
- Congress should fully fund IDEA at 40% of the average per pupil expenditure for states to meet the needs of students with disabilities.
- The Department of Agriculture should continue flexibility in delivery of food through the FRPL program, while maintaining nutrition standards as feasible.

State governments:

- State governments should require that school districts follow statewide guidance based on scientific criteria for when schools will provide in-person options versus fully remote instruction.
- State public health departments should prioritize vaccination of teachers after essential health care workers and first responders to safely have students return to in-person learning as soon as possible.

State/Local governments:

- State and/or local governments should revamp school funding formulas to reduce proportion of local funds and increase proportion of state funds; may require change to state/local tax structure.
- State and/or local governments should prioritize safely opening schools by continuing disease prevention measures in the community, such as mask mandates and restrictions on non-essential businesses and gatherings.
- State and local governments should develop and practice contingency plans for public health emergencies, including coordination between state departments of education and LEAs, state and local public health, other relevant sectors, teachers unions, and private and non-profit stakeholders.
- State and/or local governments should ensure plans include flexible reallocation of resources; procurement and distribution of PPE, technology and other resources needed for student learning; broadband access; and continuation of FRPL program to minimize service gaps.
- State and/or local governments should assess, fund and initiate infrastructure improvements, including HVAC filtration systems.
- State and/or local governments should provide funding to at-risk families for childcare, service provision and facilitation of student learning.
- State and/or local education agencies should offer teacher training and resources for online instructional delivery and professional development opportunities on meeting students' needs through trauma-informed, equity-centered strategies.
- State and/or local governments should ensure adequate funding for school nurses and social workers to help identify and refer students and families who may have health-harming needs to community service providers, including legal aid.

Local governments:

- Local education agencies should enforce mask mandates, use of PPE, social distancing, and hand sanitizing for staff and students in school facilities and buses.
- Local education agencies should collaborate to offer on-site rapid testing for teachers and students, as well as vaccination clinics for teachers and eligible students, taking into account FERPA, HIPAA, and other relevant legal issues.
- Local education agencies should ensure students have access to necessary technology at home, including broadband and individual devices compatible with assignments through both public appropriations and public/private partnerships.
- Local education agencies should provide at-risk students with additional services and supports to prevent learning loss and close achievement gaps, such as tutoring, evening classes, and summer school.

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A Pandemic Meets a Housing Crisis

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SUMMARY. As we write in early 2021, there is a COVID-19 vaccine, a new president but, unfortunately, the same racial and socioeconomic inequities attributable to housing that have become more entrenched in the fabric of this country. A person's housing status and the quality of that housing have a significant impact on the individual's health. Homelessness can be a death sentence and anything that makes it more difficult to pay rent is a step closer to losing shelter, with government intervention as the only hope. If a family can only afford to live in substandard housing with overcrowding, allergens, or in a hazardous neighborhood, this adversely impacts mental and physical health. The short-term solutions in the Coronavirus Aid, Relief, and Economic Security Act (CARES Act, 2020) and the Consolidated Appropriations Act did not begin to address decades of injustice that have exposed communities of color to health risks. The Biden administration has extended the eviction moratorium, and increased the level of federal reimbursement to states and cities that provide sheltering for people who are homeless and are also likely to experience high-risk, but federal action by itself is not enough: a multi-level approach is needed to ensure the long-term effects of the public health crisis are addressed. State and local actors must enact laws that provide resources to stave off an eviction crisis, ensure stable and affordable housing, and provide anti-poverty measures that would reduce environmental stressors that intensify and create chronic disease. This Chapter describes the pandemic's effect on racial housing and health disparities before providing details on the most important federal, state and local actions that will mitigate these injustices on a more permanent basis.

Introduction

As detailed in the first Volume of this report, people of color experience poverty, health disparities, and housing instability at significantly higher rates than white people. It is clear these injustices are heightened as a result of the pandemic, and that housing relief policies offer little more than a stopgap for a select percentage of residents, rather than taking the opportunity to address widespread systemic racism and institute long-term solutions. This Chapter will discuss the inequities in depth before setting forth concrete recommendations for action. The racial inequities exacerbated in 2020 point to two, overarching housing solutions that must be implemented in 2021. First, people who are struggling need direct, financial assistance. Second, we must keep people safely sheltered through eviction moratoria, affordable housing creation, and by addressing the underlying causes of homelessness. For more analysis and recommendations related to housing and the pandemic, please see Chapter 25 in *Assessing Legal Responses to COVID-19: Volume I.*

Housing and Health Inequities

Black and Hispanic people bear the brunt of the millions of evictions that are filed each year in the United States. Eighty percent of people facing eviction identify as non-white, with Black women facing eviction at the most disproportionately high rates (Benfer, E., et. al., 2020). Black women were evicted three times as often as white women, and 37% more than Black men from 2012 to 2016 (Benfer, E., et. al., 2020). Further, Black, Hispanic, Indigenous and Asian people are more likely to be hospitalized and die from COVID-19 (Eviction Lab, 2020). Racial disparities in housing instability and health care existed prior to the pandemic, and the factors causing both are compounding, enhancing both complications from the coronavirus and eviction rates among people of color. There are several reasons for the connection between eviction and the transmission of COVID-19. Eviction-related stressors result in weakened immune systems that are then more susceptible to the virus (Vásquez-Vera et al., 2017). The actual eviction event, which often results in families moving in with others, homelessness, or sleeping in vehicles or shelters, makes it effectively impossible to practice basic social distancing. Experiencing any of these scenarios also make it difficult to comply with hand-washing guidelines or seek health care (Benfer et al., 2020). The 11,000 coronavirus-associated deaths that occurred as a result of ending eviction moratoriums between March and September 2020 illustrate the impact that housing policies have on health (Leifheit, 2020).

The eviction moratorium included in the CARES Act passed by Congress in March 2020, as well as additional moratoria at the state and local levels slowed the rate at which people were forced out of their homes, but when such restrictions were lifted, evictions reached historic heights. Eviction Lab found that cities without protections in place saw eviction filings climb to 395% above average upon the expiration of the CARES Act (Eviction Lab, 2020). Of the 44 states that enacted eviction moratoriums in the spring, 33 of these states lifted them over the summer, and these states had twice as many COVID-19 cases and five times as many deaths as their counterparts (Leifheit, 2020). Eviction rates fell to 83% below the average upon the implementation of the Centers for Disease Control and Prevention (CDC) Order (Benfer, E., et al., 2020). The National Low Income Housing Coalition estimates that up to 40 million people believe they will not be able to pay the rent owed upon the expiration of the CDC moratorium (Threet, 2020). Given that 26% of Black renters and 18% of Latino renters had overdue rent as of October 2020, the expiration of the moratorium will continue to adversely impact people of color (Threet, 2020).

Short-term housing solutions provide only temporary relief, and this mirrors what has occurred with the poverty rate during the pandemic. The stimulus, unemployment increases, and other temporary cash assistance measures drastically reduced U.S. poverty rates in the summer of 2020 (Han et al., 2020). However, upon the expiration of these measures, poverty rates skyrocketed to all-time highs (Han, et al., 2020): 7.8 million people's incomes fell to or dipped below the poverty line between June 2020 and November 2020, with Black people being the most affected of racial groups (Han et al., 2020).

Short-Term Solutions

The amount and limits on federal housing aid underscore the importance of solutions at the state and local level. The Urban Institute estimates that $15.5 billion per month is required to provide assistance to every rent-burdened household (Shroyer et al., 2020). The pandemic relief bill that was signed into law on December 27, 2020 (the Consolidated Appropriations Act) appropriates $25 billion in emergency rental assistance (including rent, rental arrears, utilities and home energy costs, and arrears, and other housing-related expenses) administered by the U.S. Department of the Treasury to eligible, pass-through grantees, which are U.S. states, certain cities with populations of at least 200,000, U.S. territories and Tribal communities. Even if 100% of this amount is used for direct financial assistance, this is not enough to cover the monetary need for even two months. Furthermore, in considering applications for financial assistance and housing stability services by eligible households, the Consolidated Appropriations Act prioritizes households with an income that does not exceed 50% of an area's median income (AMI), as well as households in which one or more individuals are unemployed as of the date of the application for assistance and have not been employed for a 90-day period preceding that date. The additional layers of requirements are in response to the limited resources allocated to housing. Instead, the amount of resources should increase. Certainly, all families who make less than 100% of the AMI would benefit from assistance, and simply having a job does not negate an individual from being underemployed and in need. Increasing resources rather than shrinking the recipient pool is a more optimal solution. With respect to homeowners, the only assistance is to increase funds available to insure and guaranty home loans.

Unfortunately, the wave of evictions that has been anticipated for months will likely materialize. The eviction moratorium issued by the CDC on September 4, 2020, set to expire on December 31, 2020, has only been extended by three months, to the end of March 2021 (CDC Media Statement, 2021). While this order protected many more renters than the CARES Act, a slight extension in time offers no substantial assistance to any renter and certainly does not address racial inequities.

Long-Term Solutions to Mitigate Inequities

Distributing funds for rental assistance, back rent, security deposits, overdue and forthcoming utility bills, and other housing-related costs would provide a solution for sustainable mitigation of health inequities. In addition to this, more policies and laws that provide long-term solutions to health disparities caused by housing instability must be enacted in order to reduce the racial inequities that have become more pronounced by the pandemic. Ensuring that funds are quickly delivered to those in need allows people on the brink of eviction or in need of other necessities to avoid extending their state of emergency for clerical reasons. There must be sufficient inventory of affordable housing available for those in need upon receipt of the funds. Therefore, it is necessary to create and maintain housing for people who are living in poverty. The interrelated socioeconomic causes of homelessness require more than simply the construction of residences. Addressing issues such as substance abuse, mental health, education inequities and other determinants that are both a product of and enhanced by structural racism through permanent, supportive housing will help to end the cycle of poverty and instable housing that the stopgap policies we saw in 2020 failed to do.

It is of paramount importance to efficiently distribute cash directly to those who need it most. The $4.3 billion allocated to states and localities via the CARES Act to provide rental assistance stipulated that the funds be used by December 30, 2020. A lack of landlord participation and bureaucratic inefficiencies have slowed the distribution of this money. Administrative difficulties in reviewing applications, responding to requests, and distributing money have resulted in likely $300 million going unused by that deadline despite the obvious financial need (Dougherty, 2020). Financial assistance needs to be allocated directly to low-income landlords in danger of losing their properties and suffering from reduced income, and to low-income renters to avoid eviction. Funds should also be provided to organizations working directly with people experiencing homelessness in order to secure shelter and other necessary social services to reduce adverse health outcomes.

Given the deficiencies in federal action, states and localities must act quickly to pass legislation and appropriate funds for housing and financial assistance. It has been encouraging to see states, cities, and counties declare emergencies and enact ordinances that provide their residents with housing protections and rental

assistance beyond what was allocated by the federal government. New York, Connecticut, and Washington have all extended eviction moratoriums beyond January 2021 (Rubinstein, 2020). However, these extra measures were certainly the minority, and to achieve the objective of avoiding a humanitarian crisis of epic proportions due to the compounding effects of health challenges, unemployment evictions and countless other stressors, the best practices at the state and local level must be implemented nationwide.

Recommendations for Action

Federal government:

Congress should amend the Affordable Housing Credit Improvement Act of 2019 to increase the tax credit allocations by 50% in order increase the supply of affordable housing.

By the end of the first quarter of 2021, Congress should have passed an additional stimulus bill to:

- Extend the time limit on eviction and foreclosure moratorium for homeowners with Fair Housing Act-insured single-family mortgages through the end of 2021. The eligibility criteria provided in the CDC order should be used in this bill in order to increase the percentage if renters who will benefit.
- Provide loan forgiveness for three months for owners of multifamily properties with federally-backed loans.
- Increase the amount of rental assistance by at least 50% of that provided in the Consolidated Appropriations Act.

State governments:

State legislatures should appropriate funds and enact laws to provide rental assistance grants to low-income renters and to landlords to reduce evictions and rehabilitate structures with environmental hazards.

Local governments:

To prevent public housing tenants from experiencing homelessness, public housing authorities (PHAs) by rule and/or local governments by ordinance should:

- interpret emergency orders or declarations regarding evictions broadly, to freeze evictions in all forms and at all stages, including filings and notices.
- Stop the initiation or completion of evictions for non-violent or emergency reasons until after state or local emergencies are over.
- Extend the repayment period to a minimum of six months after the end of the moratorium.
- Stop the collection of any late fees during the suggested extended repayment period, even if such fees were charged prior to the beginning of the moratorium.
- Eliminate any restrictions on individuals who were evicted from private housing from the Housing Choice Voucher program.
- Provide permanent, supportive housing for people experiencing homelessness.

PHAs should exercise their authority to cease enforcement of any minimum rent during the pandemic and for a period for at least six months after.

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Using SNAP to Address Food Insecurity During the COVID-19 Pandemic

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SUMMARY. It is estimated that more than 50 million Americans experienced food insecurity in 2020 as the COVID-19 pandemic ravaged the U.S. economy. This is a devastating 42% spike in food insecurity from 2019. Recent data from the United States Department of Agriculture (USDA) indicates that 35.2 million Americans experienced food insecurity in 2019. In fact, 2019 represented a 19-year low in the national food insecurity rate. However, the USDA's 2019 data revealed that the burden of food insecurity continued to be inequitably experienced. White Americans experienced food insecurity at a rate of 7.9%, while the rates for Black Americans and Latino Americans were 19.1% and 15.6%, respectively. Preliminary studies of the 2020 food security crisis indicate that this disturbing inequity continues. Unfortunately, the economic challenges that created this drastic increase in food insecurity will linger for years. Economic projections expect the national economy to return to pre-pandemic levels in 2023. During this period of economic recovery, the Supplemental Nutrition Assistance Program (SNAP) will be vital in addressing food insecurity. This Chapter analyzes recent government actions pertaining to SNAP within the context of a prolonged economic recovery. This analysis focuses on government actions pertaining to the value of SNAP benefits and eligibility for SNAP. It also provides recommendations to enhance SNAP's ability to fight food insecurity during this public health crisis.

Introduction

As discussed in in Chapter 29 of *Assessing Legal Responses to COVID-19: Volume I*, the COVID-19 pandemic has exacerbated the food security crisis in the United States. Recently published food security data reveals that prior to the pandemic, in 2019, 10.5% of US households or 35.2 million Americans were food insecure (Coleman-Jensen et al., 2020). National food insecurity had not been this low since 2000. However, the pandemic-induced economic crisis caused a disturbing spike in food insecurity. Experts estimate that more than 50 million Americans experienced food insecurity during 2020 (Feeding America, 2020). Unfortunately, the weak economy that has led to this food insecurity is not projected to recover until 2023 (Shulman, 2020).

Even during better times, the burden of food insecurity is inequitably experienced. Prior to the pandemic, in 2019, white Americans experienced food insecurity at a rate of 7.9%, while rates for Black Americans and Latino Americans were 19.1% and 15.6% respectively (Coleman-Jensen et al., 2020). This inequity is perpetuated during the pandemic. A full analysis of the pandemic's impact on food security in 2020 is not yet available. However, a study by Feeding America found that while only 3% of all counties in the United States are majority Black, 18 of the 25 counties with the highest projected food insecurity rates were majority Black (Feeding America, 2020).

The Chapter in Volume I also discussed how SNAP could be leveraged to address this food security challenge and provided numerous legal and policy recommendations. This Chapter analyzes recent government actions pertaining to key recommendations made in the first Volume. The analysis will specifically focus on government actions that pertain to (1) increasing the value of SNAP benefits and (2) increasing the number of individuals eligible for SNAP.

Increasing the Value of the SNAP Allotment

Increase Maximum SNAP Allotment

Part I discussed the need for the federal government to increase the maximum value of the SNAP allotment, the money provided to households for the purchase of food. Three factors drove the need for this increase. First, it would provide support to the 40% of SNAP households that were already receiving the maximum allotment. Second, it would help address the baseline inadequacy of the allotment, which fails to support a healthy diet under normal

conditions. Third, SNAP provides strong economic stimulus for the larger economy.

Congress began to address the insufficiency of the SNAP allotment through the Consolidated Appropriations Act of 2021. The act increased the SNAP allotment for all households by 15% by requiring the maximum allotment value to be calculated using 115% of the thrifty food plan. For a family of four, the increase in benefits could be as much as an additional $102 per month (USDA, 2020a). This increase went into effect on January 1, 2021 and will provide needed support to vulnerable Americans.

Unfortunately, this allotment increase will sunset on June 30, 2021. This appears to be a political compromise. In the Health and Economic Recovery Omnibus Emergency Solutions Act (HEROES Act), the House originally proposed a September 30, 2021 sunset for the 15% increase. In contrast, the Senate's earlier stimulus efforts, The Health, Economic Assistance, Liability Protection, and Schools Act (HEALS Act), did not include any allotment increase for the SNAP program.

However, the Biden administration has recognized the need to extend the 15% SNAP benefit increase. President Biden's American Rescue Plan, a $1.9 trillion relief package, calls on Congress to extend the benefit increase through September 2021. He has also indicated that he is committed to providing this additional support "for as long as the COVID-19 crisis continues, and will work with Congress on ways to automatically adjust the length and amount of relief depending on health and economic conditions…" (White House, 2021). At the time of this writing, the House and Senate have passed a concurrent budget resolution and are working on the appropriations bill to implement Biden's plan (Pramuk, 2021).

While extending the SNAP benefit increase through June 2021 or September 2021 is helpful, more is needed to support the millions of Americans struggling with food security. Recently, Federal Reserve Board Vice Chairman Richard Clarida asserted that recovery from the COVID-19 recession may take until the end 2023 (Lane, 2020). Clarida's view is supported by other economic forecasts that predict that the nation's GDP will not recover until 2023 and that employment will not recover to pre-pandemic levels until "well past 2022" (Shulman, 2020). Sunsetting the SNAP increase in June or September ignores that the economic conditions driving the nation's exacerbated food insecurity still exist and economic recovery is years away. This only underscores the recommendation, made in Volume I, that the duration of any temporary SNAP benefit increase must be linked to an economic metric that reflects a decreased need for government support. The Center of Budget and Policy Priorities recommends terminating the increase when there is a decrease in the three-month unemployment rate for two straight months that results in an unemployment rate within 1.5% of the pre-pandemic level (Rosenbaum et al., 2020).

Increase Minimum SNAP Allotment

Volume I also recommended that Congress increase the minimum SNAP allotment from $16 per month to $30 per month. This increase is necessary to provide meaningful support to the approximately 1.8 million households that qualify for the minimum allotment, the majority of which include elderly individuals. The proposed HEROES Act included this increase. However, this change did not make it into the Consolidated Appropriations Act of 2021. Currently, the USDA is still approving emergency allotment waivers that allow states to issue up to the maximum allotment regardless of a SNAP household's income. However, it is unclear how long the emergency allotment will be in place. States must apply for these waivers each month and the USDA has indicated it will grant these extensions if the state meets their data reporting requirement, the federal public health emergency declaration is in place, and the state is under a state declared emergency (USDA, 2020b). This system leaves minimum allotment households vulnerable, especially if the public health emergency declarations end before the economy has recovered. As discussed in Volume I, if the federal government is unwilling to provide this support, state governments can enact legislation to increase the minimum allotment in their jurisdiction.

Increasing the Number of Individuals Eligible for SNAP

Able-Bodied Adult Without Dependents (ABAWD) Requirement

The ABAWD work requirement mandates that individuals between the ages of 18-49, who can work and do not have dependents, meet special work requirements to receive more than three months of SNAP in a three-year period. To address issues with the ABAWD work requirement, Part I made two recommendations. First, Congress should link the duration of the ABAWD work requirement waiver, passed as part of the Families First Coronavirus Response Act, to an economic recovery indicator rather than the termination of the federal public health emergency declaration. Second, the Trump administration's new regulations pertaining to the ABAWD work requirement should be repealed. These regulations greatly restricted a state's ability to (1) secure geographic waivers of the work requirement based on poor economic conditions and (2) grant struggling ABAWDs monthly exemptions to the work requirement. The repeal of these regulations was critical because 700,000 ABAWDs were expected to lose their SNAP benefits once the federal waiver expired (84 Fed. Reg. 66,792, 2019). The potential harm from this loss of benefits would be compounded because the federal ABAWD waiver was not linked to the nation's economic recovery, leaving these individuals without SNAP benefits in a weak economy with few job options.

Unfortunately, Congress did not utilize the Consolidated Appropriations Act of 2021 to link the ABAWD work requirement waiver to the nation's economic recovery. However, the problematic regulations were vacated on October 18, 2020 (*District of Columbia v. USDA*, 2020). A group of states, cities, and private entities challenged the regulations as an invalid use of agency power. In a scathing opinion, the United States District Court for the District of Columbia agreed with the plaintiffs. The court began its dissection of the regulations by invalidating them on procedural grounds. The court held that the USDA had failed to give the public notice of, and opportunity to comment on the regulatory changes as required by federal law. The court then went on to invalidate the geographic waiver restrictions as "arbitrary and capricious" because they lacked any evidentiary basis. Lastly, the court struck down the

individual exemption limitations as contrary to the agency's statutory mandate. While the USDA appealed this decision in December of 2020, it is likely that the appeal will be dropped under the Biden administration.

Ban on Individuals with Drug Felony Convictions

Finally, Volume I called for the repeal of the lifetime ban on SNAP benefits for individuals with a felony drug conviction. This ban disproportionately impacts people of color and women, undermines the food security of families, and creates barriers to reintegration. While many states have opted out or modified this ban, as permitted by federal law, it continues to undermine the food security of many Americans (Payne et al., 2020).

Congress attempted to repeal part of this problematic law through the historic Marijuana Opportunity Reinvestment and Expungement Act of 2019 (MORE Act). When the MORE Act passed the House (228-164), it was the first time a chamber of Congress had passed a bill to decriminalize marijuana at the federal level. The MORE Act also attempted to redress some of the negative societal impacts caused by the war on drugs. Key provisions of the bill included expungement and resentencing measures for federal cannabis offenses, federal funding to reinvest in communities and individuals adversely impacted by the war on drugs, and the removal of legal barriers to key federal benefits. For our discussion, it is important to note that the MORE Act prohibited a person from being denied any federal public benefit based on cannabis use or a cannabis conviction. This would have repealed the SNAP felony ban but only for individuals with cannabis convictions. Unfortunately, the MORE Act died in the Senate. However, now that control of the Senate has changed, there may be a greater chance to repeal the SNAP drug felony ban. Also, if the federal government is slow to progress on this issue, states have the authority to opt out of this ban and should do so.

Recommendations for Action

Federal government:

- Congress should:
  - Link the duration of the temporarily 15% increase in the maximum SNAP allotment to an economic recovery metric, rather than an arbitrary date.
  - Increase the minimum value of a SNAP allotment from $16 to $30.
  - Link the duration of the temporary ABAWD waiver to the nation's economic recovery, rather than the termination of the public health emergency declaration.
  - Repeal legislation that bans individuals with felony drug convictions from participating in the SNAP program (21 U.S.C. § 862a).

State governments:

- If the federal government fails to increase the minimum SNAP allotment, pass legislation to increase the minimum value of SNAP allotment within the state. This requires allocation of state funds to supplement the federal benefit.
- If the federal government fails to repeal the SNAP ban on individuals with felony drug convictions, pass legislation that completely opts out of the SNAP felony ban.

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Paid Leave and Unemployment Insurance during the Pandemic and Beyond

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SUMMARY. The pandemic has exposed and heightened the need for policies that enable all workers to stay afloat financially and care for themselves and their families during times of crisis. Two vital such policies are job-protected paid leave and unemployment benefits. Supports for working families and individuals who lost work during the pandemic have been a lifeline for many, but have not fulfilled their promise for millions more, intensifying pre-existing inequities and causing lasting harm to already marginalized communities. Despite evidence that paid sick leave saves lives, Congress let COVID-19 emergency paid leave protections expire in December 2020, in the midst of a worsening public health crisis and an unprecedented number of women leaving the workforce, often to provide care. Similarly, the extra $600 unemployment benefit expired at the end of July 2020 with only a temporary executive memorandum to follow, that added $300 to regular benefits for about six weeks. Other extensions, including extra weeks of benefits available for workers eligible for regular unemployment, and the supplemental program available for people who do not qualify for regular unemployment, lapsed on December 26, 2020. While an extension of all of these provisions was signed by the president on December 27, that delay has meant weeks-long lapses as states retool outdated systems to continue to pay benefits. This Chapter offers lessons learned and policy recommendations that center the needs of low-wage workers, women, and people of color by ensuring robust job and income protections to build a path to an equitable recovery.

Introduction

As discussed in Volume I, in March 2020, Congress enacted temporary emergency paid sick and family leave and expanded unemployment benefits, but both policies had serious gaps that left millions without crucial income and job protections. These gaps disproportionately have affected women, people of color, workers earning low wages, and immigrants. This Chapter offers lessons learned, highlighting that while these policy responses have helped avoid even graver health and economic crises, implementation barriers and gaps in coverage have contributed to disparities in health and economic outcomes for women and communities of color. With the pandemic raging and the country facing record numbers of infections and deaths from COVID-19, bold action is required to ensure that working families have the income and job protections needed to recover, care for their families, and get back to work. The Chapter concludes by offering policy recommendations to guarantee equitable paid leave and improve unemployment insurance in order to protect the health and economic security of all Americans, especially those most impacted by the pandemic.

For more information on job and income protection, please see Chapter 28 in *Assessing Legal Responses to COVID-19: Volume I*.

Paid Leave and Unemployment Insurance: Lessons Learned and Challenges Ahead

Paid Leave

As discussed in Chapter 28, Volume I, the Families First Coronavirus Response Act (FFCRA) enacted in March 2020 represented the first time the federal government guaranteed workers the right to paid leave. The Act provided two weeks of emergency paid sick leave for a variety of reasons specific to COVID-19 health and caregiving, and 12 weeks of emergency paid leave for parents whose children's schools or child care was closed, virtual, or unavailable. A temporary measure effective April 2020 through December 2020, it applied only to employers with fewer than 500 employees, and granted employers of health care providers and emergency responders the ability to deny workers' requests for leave. It also allowed businesses with fewer than 50 employees to deny leave to parents who needed to care for children whose schools or child care were unavailable.

A recent study found that the emergency paid sick leave requirement of the FFCRA helped slow the spread of the virus, leading to 417 fewer reported cases of COVID-19 per state per day in places where workers gained access to paid sick leave as a result of the FFCRA (Pichler et al., 2020). These findings comport with prior research showing that workers are more likely to follow public health guidance and stay home when sick if they know they their jobs and pay are secure.

While a critical part of the country's response to COVID-19, the FFCRA had major shortcomings, excluding millions of workers, disproportionately those earning low wages who were on the frontlines of the crisis in large chain grocery stores, pharmacies, restaurants, retail stores, warehouses, and health care settings. In September 2020, the Department of Labor (DOL) narrowed the scope of the health care provider and emergency responder exemptions to the FFCRA as a result of a federal court's invalidation of the prior regulation as overbroad. Even still, millions of workers were left out from the paid leave requirements, with workers earning low wages and workers of color more likely to be excluded. Similarly, the Department of Health and Human Services found that the parents most likely to be excluded as a result of the small business exemption were disproportionately low-income workers (Meade & Winston, 2020). These gaps exacerbated pre-existing disparities, as those falling through the cracks were also less likely to have employer-provided paid leave or the ability to work from home.

Beyond gaps in coverage, experience with implementation has revealed other significant barriers to access. Many workers who were eligible for FFCRA found themselves needing more than the two weeks of leave provided because they experienced complications from COVID-19. And given the increasing level of community spread, countless essential workers — many of whom live in multigenerational or multifamily households — have faced multiple exposures, each instance requiring them to quarantine for up to two weeks, even though they may have exhausted their sick leave entitlement with the first exposure. While some states and localities stepped in to fill the gaps in FFCRA coverage, these laws typically covered narrower reasons for leave, and did not extend the total duration of paid leave available, nor did they provide a new bank of leave for each qualifying circumstance. As the study assessing the impact of the FFCRA noted, "If employees take their emergency sick leave as a precautionary measure or because they are quarantined for the standard time of two weeks, they obviously are unable to take paid sick leave again, which may force them to work sick and potentially spread the virus in the future" (Pichler et al., 2020).

The child care leave provision of the FFCRA also proved insufficient, plagued by the same gaps in coverage and inadequate duration of leave. Though this provision afforded 12 weeks of leave, by the end of 2020, millions of families had gone without in-person school or child care for many months. Further, as noted in Volume I, the wage replacement rate for caregiving and child care leave under the FFCRA was far too low.

Moreover, an Inspector General report found that the DOL was not adequately implementing or enforcing FFCRA claims (OIG, 2020). The agency waited four months after passage of the Act to launch a public awareness campaign, only after advocates had urged them to do so for months (Chapin, 2020). As a result, a June poll found that 44% of voters had heard nothing or very little about the emergency paid sick days law, and the majority of voters (54%) had heard nothing or very little about the extended school closure/child care leave (Lake & Carpenter, 2020). State and local efforts to educate workers about paid sick leave likewise have had varying levels of success, in part due to the complexity and rapidly changing nature of the laws. Some initiatives to disseminate information about paid leave via public health channels like COVID-19 testing and contact tracing, as well as through community-based organizations, have shown promise, but have not been adopted systematically.

These barriers have hampered the ability of the FFCRA to keep working parents, especially mothers, employed. Women have always shouldered the bulk of family caregiving, and the pandemic has only exacerbated the caregiving crisis, requiring even more care for children, elderly relatives, and ill loved ones. These factors have contributed to an exodus of women from the labor force, particularly for women of color, who are also overrepresented in sectors with the greatest pandemic-induced job losses such as care and service work (Madowitz & Boesch, 2020). In September 2020 alone, 865,000 women left the workforce, compared to 216,000 men (Long, 2020). An analysis by the National Women's Law Center found that in December 2020, the U.S. economy lost 140,000 jobs, all of which were held by women (Ewing-Nelson, 2021). In all of 2020, 2.1 million women dropped out of the labor force, including 564,000 Black women and 317,000 Latinas (Ewing-Nelson, 2021). As of December, Asian women had the highest rates of long-term unemployment (Ewing-Nelson, 2021). Without equitable paid leave and other policies that center the needs of women of color and workers earning low wages, this "she-cession" will have a long-lasting impact on the economic stability of women, families, and entire communities.

Yet rather than fix the problems with the FFCRA and expand coverage to all workers, Congress let the right to paid leave lapse entirely at the end of 2020. This decision came at the precise moment that the virus was raging across the country, with people of color experiencing higher infection and death rates due to enduring systemic racism and social and economic inequities, including lack of access to paid leave. The Consolidated Appropriations Act enacted in December 2020 extended tax credits for employers who *voluntarily* provide paid leave under the FFCRA through March 2021, but failed to extend the emergency paid leave requirement itself. Moreover, the tax credits are only available to employers who were previously covered by the FFCRA, and only for leave given to workers who had not already exhausted the entitlement in 2020. Many of the state and local emergency paid leave laws that filled the gaps in the FFCRA were tied to the duration of the federal Act, and also expired at the end of 2020. As a result, on January 1, 2021, as many as 87 million workers across

the country lost the right to paid leave at a time when the country faced a record death toll from COVID-19, hospitals were filling up, many schools and daycares remained closed, and an even more contagious variant of the virus was spreading. Compounding these challenges, Americans will now also need time off work to receive the vaccine and recover from any associated side effects. The need for universal, equitable paid leave policy is therefore more urgent than ever.

Unemployment Insurance

Prior to the COVID-19 pandemic, it was clear that unemployment systems were ill-prepared for a recession (Evermore, 2019). However, the lengthy delays in initial certification and recertification greatly exceeded all expectations. Most importantly, researchers at the California Policy Lab have discovered that the number of people filing new claims has continued to remain steady for months. The economic recovery is taking longer in lower income communities. Even though it is much more difficult for Black and Latino workers to receive benefits, the share of Black workers within the workforce in California recertifying for benefits weekly is two and a half times the share of the white workforce claiming benefits (Bell et al., 2020).

States have experienced great difficulty paying benefits in a timely manner. First, they entered this recession with historically low administrative funding while claims were at a historic high. To put things into perspective, the highest number of new claims on record was 695,000 in a week in October 1982. Starting in mid-March 2020, a week of 3.3 million new claims was followed by two weeks in a row of 6.6 million new claims. From the start of the pandemic through January 2021, more than a million new claims were filed every single week. Outdated technology systems played a major role in lack of access. Only 16 states had fully upgraded their systems from 1970s COBOL mainframes by the start of the pandemic, and some of those upgrades were designed to keep claimants out of the system, such as the CONNECT system in Florida. All state systems have been over-calibrated to detect overpayments to the detriment of paying legitimate claims. A strike team commissioned in California pointed out a problem that likely is true in most states — the flags designed to stop overpayments only stopped regular applicants. Meanwhile, a sophisticated international fraud ring that attacked states was not deterred, only actual claimants answering questions in ways that raise flags. States have stopped payments on millions of claims due to this ring, and clearing flagged claimants can take weeks or months.

While fraud is generally rare in unemployment insurance (UI) programs in general, this crime ring appears to be using data breaches to impersonate workers and apply for benefits on their behalf. It has hit most, if not all, of the 53 jurisdictions and has resulted in millions of claims for innocent unemployed workers to be flagged as potential fraud, leaving the burden on those claimants to prove who they say they are and holding up benefits for weeks or months. As a result, states are also now implementing identity verification software in response to attacks from the crime ring. However, identification requirements in the context of voting laws have proven to create a hurdle to access for people of color, rural voters, people with limited English proficiency who have difficulty navigating identification software, and people with low incomes. While identity is largely required for much work, it is unclear whether new identification requirements will affect access to unemployment.

The omnibus and relief package that passed Congress and was signed by the president on December 27, 2020, contained several key provisions that extended benefits and added important protections. First, existing programs were extended by 11 weeks, and people who qualify for those benefits but have not exhausted eligibility can continue to receive these benefits up to and including the week of April 5, 2021. It also extended important provisions of FFCRA and CARES through March 14, 2021, such as full federal funding of a permanent program that extends regular UI benefits during periods of high unemployment called Extended Benefits, a temporary waiver on interest usually charged to states when they have to borrow from the federal government when their state trust fund runs out, and 50% reimbursement for non-profit, state and municipal employers who do not pay UI taxes but reimburse the state for benefits claimed.

The relief package also offered critical technical fixes including adding a waiver for accidental Pandemic Unemployment Assistance (PUA) overpayments. This was critically important, as PUA was a new program set up quickly, often staffed with inexperienced personnel, was available to people who do not traditionally qualify for unemployment compensation and therefore inexperienced in filing claims, and agency guidance shifted over time. Three changes to PUA were issued in 2020, and many states received letters from the DOL Employment and Training Administration and Office of Inspector General informing them that they were improperly implementing the program. Given all of these factors, millions of claimants who made innocent mistakes will be flagged as overpaid, and given that it has taken states some time to seek out overpayments, those overpayments will represent tens of thousands of dollars per claimant.

Finally, a major problem with taxes is looming. Claimants are going to be surprised with a tax bill in the thousands of dollars for most of their earnings for last year. The massive international fraud ring that has attacked state UI systems did so largely through identity theft. Claimants who have been impersonated may receive a government income tax form called a 1099-G in the mail that they do not know what to do with. Some impersonators, however, may have changed the address on record for the purposes of tax reporting, so ID theft victims will not find out that they had a government tax liability until after they have filed and are awaiting their tax return. For example, the state of California did not offer federal tax withholding FPUC benefits. However, these benefits are indeed taxable. Other states, like Ohio, did not offer state tax withholding of benefits that are indeed subject to state tax.

Conclusion

Paid leave and unemployment insurance are essential parts of the country's response to COVID-19, providing lifesaving support to workers impacted by the pandemic. But gaps in coverage and implementation barriers have hindered the success of these

policies and aggravated inequities, causing lasting harm to marginalized communities. Below are key recommendations to ensure that all workers, especially women and people of color, have the job and income protections they need to recover from the ongoing health and economic crises.

Recommendations for Action

Federal government:

- Congress should pass permanent structural paid leave reform to ensure universal, equitable, inclusive, comprehensive paid sick days and paid family and medical leave for all workers, including for workers' own health, caregiving, and bonding, as well as for COVID-19-related needs such as vaccinations and associated side effects and emergency child care, to protect jobs and economic stability during the pandemic and beyond.
- Congress should reimburse the cost of COVID-19-related leave for state and local government employers and private employers with fewer than 500 employees, covering the full range of reasons including for a worker's own illness and caring for others as well as for vaccinations and associated side effects and emergency child care, for the duration of the pandemic.
- The Internal Revenue Service and DOL should coordinate to monitor whether employers requesting tax credits have followed the law and do not have any FFCRA complaints pending against them.
- DOL should vigorously enforce paid leave protections and conduct a robust multi-lingual education and outreach campaign, including through partnering with public health systems and community-based organizations, to ensure that all workers are aware of and can meaningfully access their rights to paid leave.
- Congress should appropriate sufficient funding for DOL to establish a central Information Technology initiative to help states dramatically improve unemployment compensation infrastructure. This funding should also provide for states to upgrade their technical infrastructure and business processes centering the user experience of groups most likely to have difficulty accessing benefits, including people with disabilities, people with limited English proficiency, people with limited access to computers, and centering Black, Latino, Asian, and Indigenous communities.
- Congress should establish clear minimum requirements for state unemployment programs to ensure greater access to benefits and much higher replacement of prior income, as base income has been stagnant for far too long, establish a national definition of employee that includes more workers in the gig economy, and extend benefits to other workers not currently eligible for benefits, such as undocumented workers.
- Congress should end federal taxation of unemployment benefits.
- Either federally or at the state level, governments should immediately commission a new study to determine whether new identity verification requirements had a disproportionate impact on already underserved communities. This could be instructive nationally as all states will be required to establish identity verification systems as a result of a provision in the new federal relief act.

State governments:

- State labor agencies should coordinate with DOL on enforcement of and comprehensive multi-lingual outreach campaigns regarding federal, state, and local paid leave rights, and their interaction, including through partnerships with public health systems and community-based organizations.
- State legislatures should offer work sharing, which allows employers to spread layoffs across hours instead of laying individuals off entirely, allowing everyone to remain employed at fewer hours and get unemployment for hours lost, and expand applicability of those programs.
- State legislatures should end state taxation of unemployment benefits.

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The authors thank Sean Peters for his research assistance, and Sarah de Guia, Katie Wutchiett, Jenna Gerry, the Job Quality team at the Center for Law and Social Policy, and Vicki Shabo from New America for their thoughtful comments.

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Gaps in Worker Protections that Increase Essential Workers' Exposure to COVID-19

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SUMMARY. States and localities designated more than 55 million Americans as essential workers. Essential workers not only comprise those employed by the health care and food and agriculture industry, but also include teachers, grocery store workers, transit and airline workers, mail and delivery workers, energy sector and utility workers, and domestic workers (Petition for Emergency, 2020). Racial and ethnic minorities are disproportionately employed as essential workers, with Black Americans the most likely to be essential workers (Petition for Emergency, 2020). Essential workers have been left vulnerable to workplace COVID-19 infections and deaths in large part due to the federal and state government's failure to enforce health and safety laws (Yearby, 2020). Volume I discussed the need to issue airborne infectious disease specific laws and regulations to prevent workplace COVID-19 infections and deaths. This Chapter will examine how the lack of protective equipment, punitive attendance policies, and the failure to track workplace infections have left essential workers vulnerable to workplace COVID-19 infections and deaths.

Introduction

During the pandemic, health care workers have provided critical medical care to patients; grocery store workers, farm workers, and meat processing workers have continued to feed the country; mass transit, transport, and airline workers have delivered essential goods; while utility and communications workers have sustained access to fundamental human needs of water, electricity, and internet (*Amalgamated Transit Union v. Azar*, 2020). These workers have continued to work during state and local stay-at-home and lockdown orders, despite being left without protection from workplace COVID-19 exposure. Many of these workers are racial and ethnic minorities.

Data from the U.S. Bureau of Labor Statistics shows that 38% of Black workers were employed in jobs deemed essential compared with 27% of white workers (Petition for Emergency, 2020). More specifically, "43% of Black and Latino workers are employed in service or production jobs that for the most part cannot be done remotely," while approximately 25% of white workers held such jobs (Petition for Emergency, 2020). In the health care industry, "Black workers are about 50% more likely to work in the health care and social assistance industry and 40% more likely to work in hospitals, compared with white workers," while in the food and agricultural industry a majority of workers are racial and ethnic minorities (Petition for Emergency, 2020). Consequently, racial and ethnic minorities have disproportionately been exposed to COVID-19 in the workplace because of structural inequities. Specifically, the government has failed to enforce health and safety laws and permitted essential business to remain open in spite of being sites of COVID-19 outbreaks, prioritizing the needs of employers above those of essential workers, which has resulted in increased workplace exposure to COVID-19.

For more information on Protecting Workers that Provide Essential Services, please see Chapter 26 in *Assessing Legal Responses to COVID-19: Volume I*. This Chapter will examine how the lack of protective equipment (PPE), punitive attendance policies, and the failure to track workplace infections have left essential workers vulnerable to workplace COVID-19 infections and deaths.

Worker Safety during COVID-19

As discussed in Volume I, the Occupational Safety and Health Administration (OSHA) and 21 states with OSHA-approved plans have the authority to require private employers to provide employees with personal protective equipment and develop a respiratory protection standard to prevent occupational disease (Respiratory Protection, 2019). Moreover, under the OSH Act, employers have a "general duty" to provide employees with a place of employment free from recognized hazards that are causing or likely to cause death or serious harm. Nevertheless, OSHA and many states have not ensured that essential workers are provided with PPE or a workplace free from recognized hazards.

Lack of Protective Equipment

During the pandemic, OSHA and many states with OSHA-approved plans have not used their authority under 29 C.F.R. § 1910.134 to require employers to provide employees with PPEs. For example, in Tennessee, a state with an OSHA approved plan, a health and safety official OSHA said in early May 2020 that, "the only standard sanitation requirement Tennessee OSHA can govern is that employers provide soap and water for employees" because, "by TOSHA standards, face masks are not considered personal protective equipment, and the standard does not require an employer provide them" (Massey, 2020). The failure to require face masks is contrary to the OSH Act that requires employers to provide personal protective gear, including respirators at no cost to the employee, to address respiratory issues, which cannot be addressed simply by washing one's hands (Respiratory Protection, 2019). Thus, it is not surprising that during this time, the COVID-19 infections in Tennessee went from 163 on May 1, 2020 to 566 on May 23, 2020 as a result of infections among essential workers (Massey, 2020). The federal government has also failed to use the Defense Production Act of 1950 (DPA) to obtain PPEs for essential workers.

President Trump issued three executive orders to increase the adequate distribution of PPE to essential workers, alluding to the powers granted by the DPA, yet essential workers still lack adequate access to PPEs (Petition for Emergency, 2020). Executive Order (EO) 13909 authorized the Secretary of Health and Human Services (HHS) Azar in consultation with the secretary of commerce and the heads of other executive departments to prioritize and allocate PPE to respond to the spread of COVID-19. EO 13910 authorized Secretary Azar to designate PPEs as critical materials to prevent hoarding, while EO 13911 authorized Secretary Azar and the secretary of homeland security to expand production of PPEs using loans and loan guarantees as well as coordinating industry production through voluntary cooperation (Petition for Emergency, 2020).

Additionally, on April 2, 2020, President Trump issued a memorandum giving HHS Secretary Azar the authority to acquire, "from any subsidiary or affiliate of 3M Company, the number of N-95 respirators that the Administrator determines to be appropriate," to respond to the spread of COVID-19. By April 7, 2020, the federal government had agreed to a deal with 3M to import more than 166 million N-95 respirators to the United States over a three-month period, while allowing 3M to still export respirators to Canada and Latin America. Nevertheless, many essential workers still remain without N-95 respirators or other personal protective gear, as illustrated by health care workers lack of access to PPEs.

Many health care workers who have requested access to PPE or spoken out about the lack of PPE have not only not received the PPE, but many have also been disciplined or fired. For example, a registered nurse and other colleagues filed multiple OSHA complaints regarding workplace safety violations at a Minnesota hospital. Although the hospital was eventually fined for failing to comply with the respiratory standard, the nurse was fired and the licensure board is investigating his conduct of wearing hospital supplied scrubs to protect himself from COVID-19 infection (Basen, 2020). An emergency physician in Washington state was also fired for publicly identifying the hospital's failure to provides staff with adequate PPE and gaps in COVID-19 protections (Eldred, 2020). The retaliation and lack of PPE was so rampant in the health care industry that several medical societies, including the Council of Medical Specialty Societies that represents 800,000 physicians, issued statements urging the government to ensure that health care workers had adequate PPEs (Eldred, 2020).

Notwithstanding these actions, the EOs, and the memorandum, many essential workers still lack access to PPEs. Thus, on August 11, 2020, more than 30 leading labor unions and environmental groups representing more than 20 million workers and members, including the American Federation of Labor and Congress of Industrial Organizations (AFL-CIO) and the Service Employees International Union (SEIU), submitted an Emergency Rulemaking Petition for access to PPEs "pursuant to the Administrative Procedure Act, 5 U.S.C. § 551, et seq. demanding" that the federal government, including HHS, invoke their delegated authorities under the DPA to manufacture and allocate PPE for the protection of essential workers (Petition for Emergency, 2020).

Essential workers access to PPEs did not improve after the petition was issued, and HHS did not use its powers to increase access to PPEs. Therefore, on October 8, 2020, the same 30 leading labor unions and environmental groups filed a complaint for declaratory and injunctive relief in the U.S. District Court for the District of Columbia challenging the federal government's failure to use its powers to attain PPEs for essential workers (*Amalgamated Transit Union v. Azar*, 2020). Meanwhile, health care workers continue to be infected, which has severely harmed racial and ethnic minorities. For example, a National Nursing Union report from September 2020 showed that nurses of Filipino descent comprise 31.5% of nurse deaths from COVID-19, but only account for 4% of the nursing population.

Punitive Attendance Policies

Punitive attendance polices have also increased essential workers workplace exposure to COVID-19. Before the COVID-19 pandemic, some industries attendance policies were punitive. For example, meat and poultry processing companies' issued points for workers that missed work. Workers that accumulated too many points were fired (Schlitz, 2020). These policies have persisted throughout the COVID-19 pandemic as some of the biggest meat and poultry processing companies (JBS, Smithfield, and Tyson) actively penalize workers for taking time off, even if it is for illness (Schlitz, 2020). Meat and poultry processing workers at Tyson and JBS note that they are required to go to work even if they are experiencing symptoms of COVID-19 or awaiting test results (Schlitz, 2020).

In fact, one Tyson plant does not approve prearranged absences for things such as testing, unless it does not affect the production needs of the plant. Furthermore, excused absences for COVID-19 are only given if a worker has physician documentation of a positive COVID-19 test, otherwise the worker is assessed points, which can be used to fire them (Brown, 2020). This was confirmed by JBS spokesperson Nikki Richardson, who noted that "points were not

assessed against team members for absences due to *documented* illness" (Brown, 2020).

For instance, at the JBS plant in Greeley, CO, where six workers died and 290 were infected with COVID-19 in July and 32 workers tested positive for with COVID-19 in November, 2020, the attendance policy allowed for six points for absences before firing, which was less than the seven and a half points allowed before the pandemic (Schlitz, 2020). Workers could only recoup points by getting physician documentation of a positive COVID-19 test and calling an English-only attendance hotline. This policy disproportionately harmed some racial and ethnic minorities, who do not speak English or have a physician to write the note (Schlitz, 2020). To address this problem, JBS promised to provide workers with free COVID-19 tests after COVID-19 outbreaks at the plant. However, instead, JBS offered the low-wage and uninsured workers COVID-19 tests at its plant if they paid $100, which workers declined (Brown, 2020).

Punitive attendance policies are associated with increased rates of infection because many workers either cannot obtain physician documentation of a COVID-19 infection or fear being assessed points, and thus, they continue to go to work sick. Moreover, these punitive attendance policies seemingly contradict the OSH Act "general duty" standard. The policies encourage employees with COVID-19 symptoms to come to work, increasing workplace COVID-19 exposure, which is a recognized hazard causing or likely to cause death or serious harm, for healthy employees. It is hard to determine the full impact of these attendance policies on COVID-19 infections and deaths because OSHA and many states are not actively and accurately tracking workplace infections.

Failure to Track Workplace Infections

OSHA and many states have either not required employers to record and report employee's COVID-19 infections and deaths, or refused to release the information, which is necessary for contact tracing and surveillance. (Michaels, 2020; Pattani et al., 2020; Pfannenstiel, 2020). For example, nursing home residents account for 8% of all COVID-19 cases and more than 40% of all COVID-19 deaths in the United States, but there is no data regarding how many nursing home workers have been infected or died, because OSHA has let nursing homes decide whether to report the infections and deaths (Pattani et al., 2020).

Research shows that between 6% to 8% of all the COVID-19 cases and 3% to 4% of all COVID-19 deaths in the United States are tied to meat and poultry processing plants (Taylor et al., 2020). When the Centers for Disease Control and Prevention (CDC) issued a report in May 2020, there were 16,233 confirmed cases of COVID-19 infections for meat and poultry processing workers and 86 COVD-19 related deaths in 239 plants (Waltenburg, et al, 2020). Of the 9,919 (61%) cases with racial and ethnic data, 56% of COVID-19 cases occurred in Latinos, 19% occurred in non-Latino Black people, 13% in non-Latino whites, and 12% in Asians. Yet, even the CDC acknowledged that the actual numbers of COVID-19 infections and deaths for meat and poultry processing workers were probably higher because only 23 states submitted data and "only plants with at least one laboratory-confirmed case of COVID-19 among workers were included" (Waltenburg, et al, 2020). Notwithstanding this report, the federal government is not regularly tracking these deaths and many states that have experienced COVID-19 outbreaks are not releasing the information as shown by Iowa, a state with an OSHA approved plan.

Prior to major COVID-19 outbreaks at meat and poultry processing plants, Iowa's policy was to publicly confirm cases. However, by May this changed when officials would only confirm outbreaks at businesses if 10% of a company's employees tested positive and reporters asked about the outbreaks (Pfannenstiel, 2020). This hampered reporting of cases and local officials' efforts to control infections as the state even limited information given to local officials, including Perry city officials, where it was later learned that 58% of employees tested positive at a Tyson plant in Perry city (Pfannenstiel, 2020).

In Missouri, when efforts to use private firms to track state employees infected with COVID-19 failed, the state health department issued a statement saying that many local health departments would no longer conduct contact tracing of positive tests. Instead, the state recommended that those who tested positive should contact close contacts on their own. However, this ignores the fact that state employees interact with numerous members of the public during work, and do not have the ability to contact these people.

The government's failure to use its authority under the DPA and health and safety laws to ensure that essential workers have access to PPEs, can stay at home when they are sick, and are contacted about workplace infections has left essential workers vulnerable to workplace exposure to COVID-19. As a result of the government's inaction, workers have continued to be unnecessarily infected and die from COVID-19. These structural inequities have disproportionately harmed racial and ethnic minorities, who make up a majority of essential workers, resulting in racial inequities in COVID-19 infections and deaths. To address these inequities, the government must not only increase enforcement, but also empower essential workers to participate in addressing workplace COVID-19 infections.

Recommendations for Action

These recommendations are based in part on state and local government examples. Virginia, California, and New Mexico "have issued emergency regulations to require employers to report COVID-19 cases, regardless of whether the infection results in hospitalization, so a rapid investigation can be made" (Michaels, 2020). California and Michigan require employers to provide employees with clean PPE, while the Los Angeles County supervisors unanimously approved a program "in which workers from certain sectors will form public health councils to help ensure that employers follow coronavirus safety guidelines" (Miller, 2020; Ball, 2020; Personal Protective Equipment, 2020). These laws and programs should be used as a model for changes in the governmental response. The Biden administration has already issued an executive order and a COVID-19 plan with recommendations to address these issues, but the recommendations are not mandatory. Below are some suggestions for mandatory laws and policies.

Federal government

President and Congress

- Enact a national workplace safety law that includes an airborne infectious disease rule, which prohibits punitive attendance policies and requires employers to report COVID-19 infections and deaths to the CDC and state and local health departments.
- Create employee safety boards that advise the White House, Congress, OSHA, and the USDA in the creation, implementation, tracking, and evaluation of a national COVID-19 worker protection plan and agenda.
- Develop a national COVID-19 worker protection plan, which requires all employers to develop and implement infection control plans, and provides protection for workers who raise safety concerns.
- In COVID-19 economic relief bills, require states to use part of the money to invest directly in racial and ethnic minority communities severely and disproportionately impacted by COVID-19, including money for culturally appropriate and multilingual mental health services for those tested positive and their family members and friends.

OSHA and States with OSHA Approved Plans

- Mandate testing of workers employed at essential businesses that are hotspots for COVID-19, including, but not limited to hospitals, long-term care facilities, meat and poultry processing facilities, farms, and food processing facilities.
- Make this testing data, which does not include individually identifiable information, publicly available and disaggregate by race, ethnicity, job duty, and occupation to determine businesses that are hotspots for COVID-19. This data should be readily accessible to the workers, state and local officials, and the media.

State governments

- Enact a statewide workplace safety law that includes an airborne infectious disease rule, which prohibits punitive attendance policies and requires employers to report COVID-19 infections and deaths to the health department.
- Create employee safety boards that advise state, county, and local governments in the creation, implementation, tracking, and evaluation of a national COVID-19 worker protection plan.

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Liability, Liability Shields, and Waivers

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SUMMARY. COVID-19 lawsuits are not easy to win. Viral transmission of COVID-19 remains possible even where reasonable care is taken and litigation against cohorts such as employers, health care providers, and nursing homes is already difficult. Notwithstanding, both health care providers and re-opening businesses (as well as essential businesses and nursing homes) have lobbied hard for liability shields. About half the states have listened to their entreaties, passing various narrow to broad immunities that may deter litigation at least until courts grapple with their constitutionality and interpretation. In addition, some businesses have deployed exculpatory clauses in their contracts or signage refuting any liability for injury or damages. Courts have various doctrines in place for analyzing these clauses including voiding them if they impact necessary services.

Introduction

The *Volume I* assessment examined the potential liability of businesses and medical professionals for acts and omissions involving COVID-19, and provided an analysis of long-established, new and contemplated federal and state liability shields. At the time of publication, that Chapter noted a number of state liability waivers, typically applicable to health care providers and usually promulgated as part of gubernatorial emergency orders. Also noted were some early "re-opening" shields designed to protect other businesses such as restaurants (Terry, 2020).

Since then, state legislatures have been far more active, turning their attention to re-opening waivers of varying scope. This Chapter will identify the trends in the waivers now passed or proposed. Additionally, it will expand on a topic only briefly discussed in the earlier Chapter: the use of waivers or exculpatory clauses that seek to create an affirmative defense that would excuse the negligent conduct of businesses in their mitigation of COVID-19.

Updates

COVID-19 Lawsuits

There has been a large but not overwhelming number of COVID-19 lawsuits filed against cruise lines, nursing homes, health care facilities, and general businesses (Hunton Andrews Kurth, 2021). From the earliest days of the pandemic the health care businesses at the highest risk of virus outbreaks and, subsequently, legal risks have been long-term care facilities. A generally for-profit industry with a woeful quality and safety record, the long-term care industry swiftly became the largest incubator of COVID-19 and the locus for the largest cohort of cases (more than one million by early 2021) and deaths (more than 130,000) (KFF, 2021). Plaintiffs have brought lawsuits, including class actions, for injuries or death that residents, their visiting relatives, and staff members have suffered. Frequent allegations include substandard infection control, failure to isolate residents with symptoms, insufficient staffing, and a lack of personal protective equipment (PPE).

During the first peak in spring 2020, hospital emergency departments were overrun, and shortages of staff, PPE, ICU beds, and ventilators threatened patient care. In successive surges, PPE supply chains proved more resilient and, with the undersupply of personnel being country-wide, professionals became less likely to travel to assist in other states. Further, information had improved about which drugs, antibodies, and treatment protocols were effective and, as important, which were not. However, the magnitude of the winter 2020/2021 surge again overwhelmed hospital bed and ICU availability. The knock-on effects included delayed elective surgery and, where delay was not possible, hospital-acquired infection — the potential exposure of non-COVID patients to the virus. These scenarios all involve some legal risk for providers.

In mid-2020 the number and range of businesses that re-opened expanded considerably. States or counties controlled the cadence of the closing, restricting occupancy, or re-opening of these businesses. Over time, however, high-risk endeavors including bars, restaurants, gyms, personal care services, places of worship, schools, and colleges re-opened. Many of these activities endangered people other than the businesses and their customers. For example, there is a strong correlation between the re-opening of universities and increased cases and deaths in their communities. Throughout the pandemic, and often in violation of state or county occupancy limits, we have witnessed infections and deaths associated with obviously dangerous super-spreader events including weddings and political rallies. These, too, invited legal risk.

Exactly what type of risk depends in large part on the identity of the defendant. The standard of care in most cases will be ordinary negligence, posing to the jury the question of whether the defendant acted as a reasonable person in all the circumstances. In contrast, some but not all cases brought against health care providers may be categorized as medical malpractice and turn on expert testimony as to whether there was compliance with the professional standard of care. However, non-medical negligence allegations such as an absence of supplies or lack of infection control only require a showing of ordinary negligence. A small number of cases may attract intentional tort liability. For example, there have been reports of people objecting to mask rules or other restrictions — deliberately coughing on others or boarding an aircraft when knowingly symptomatic, for example. As with actions brought by individuals against those they believe transmitted the HIV virus to them, these will be pursed on intentional and reckless causes of action (*Doe v. Johnson*, 1993). Some defendant cohorts will be subject to specific statutory claims that may be more amenable to action such as elder abuse or qui tam Medicaid fraud suits against nursing homes.

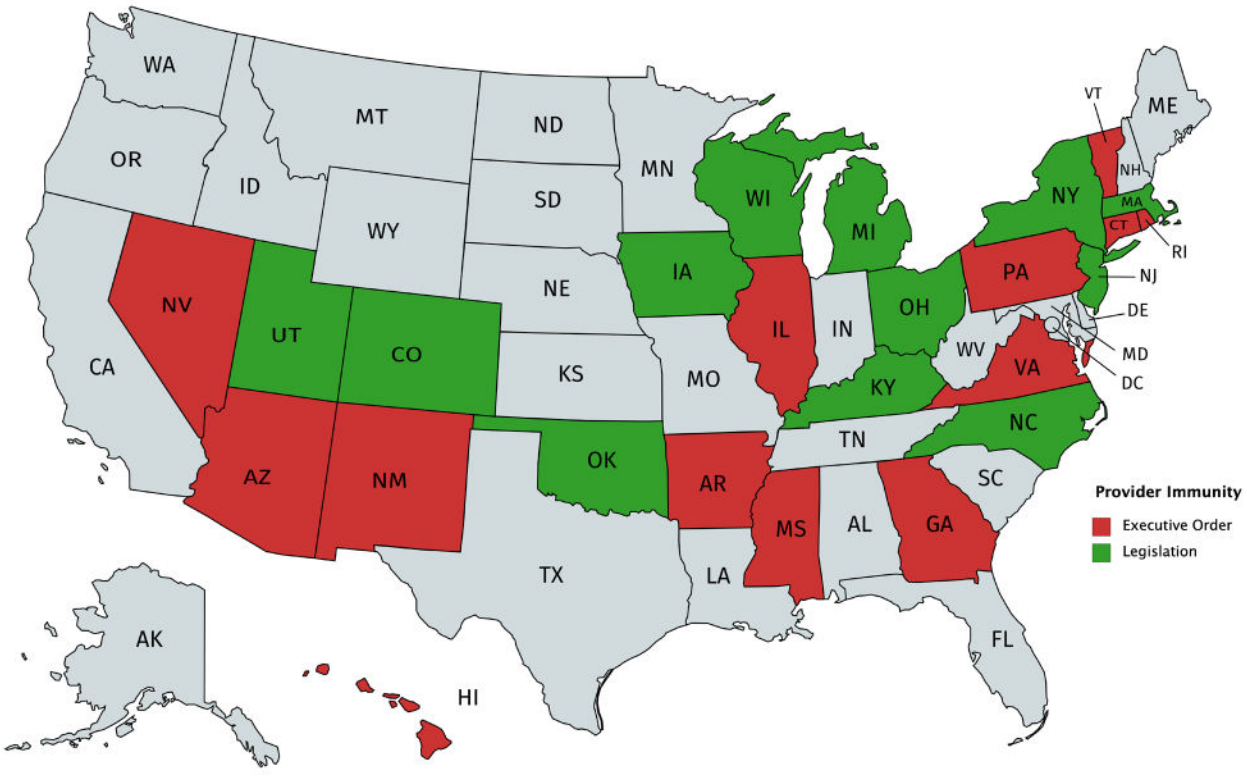
Liability Shields

Federal shields. As discussed in Volume I, liability shields for private actors under federal law are limited, consisting of The National Childhood Vaccine Injury Act of 1986, The Volunteer Protection Act of 1997, and The Public Readiness and Emergency Preparedness (PREP) Act of 2005 (Terry, 2020).

The PREP Act applies to "covered countermeasures," principally drugs, devices, and vaccines used to fight a national emergency that cause death or serious physical injury, and shields manufacturers and others in the supply chain. In addition to immunity, the PREP Act includes the Countermeasures Injury Compensation Program (CICP) that provides benefits to individuals who sustain a serious physical injury or die. The immunity does not extend to willful misconduct.

The PREP Act itself, or the Secretary's Declaration made thereunder, have been amended several times during the pandemic. In March 2020, the PREP Act was amended by the Families First Coronavirus Response Act to include "personal respiratory protective devices." Subsequently, the Secretary extended the Declaration to include respiratory protective devices (April 2020), pharmacists providing immunization (August 2020), and those using telehealth to administer countermeasures (December 2020) (Department of Health & Human Services, 2021). In the first COVID-19 case to argue PREP, a federal district court held that the argument that the Act protected a nursing home from state law liability was insufficient to justify removal of the case to the federal courts (*Estate of Maglioli v. Andover Subacute Rehabilitation Center I*, 2020). In a January 2021 advisory opinion, the U.S. Department of Health and Human Services took the position that the PREP immunity would apply to non-use or non-administration of countermeasures — common allegations against long-term care facilities (HHS Office of General Council, 2021). The opinion's broad reading of the immunity is contrary to at least one district court ruling (*Lutz v. Big Blue Healthcare*, Inc. 2020).

Figure 31.1



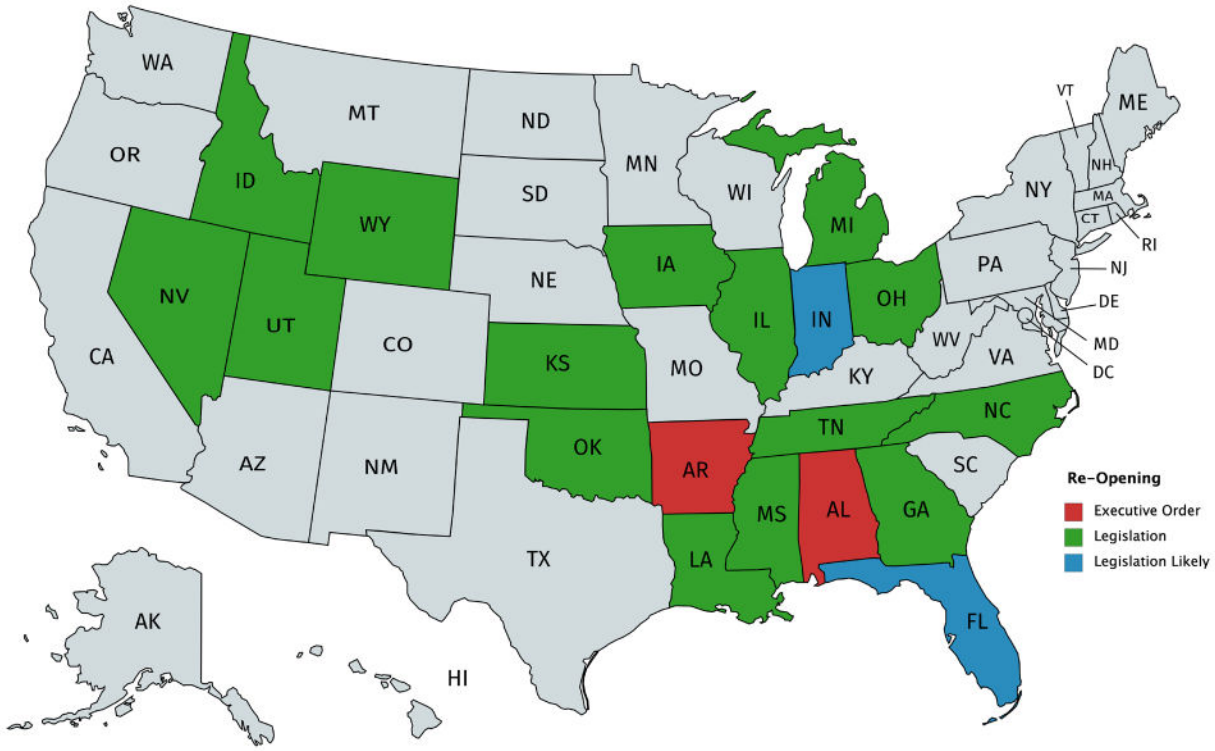


Figure 31.2

Beginning in July 2020, then-Senate Majority Leader McConnell announced that any post-CARES pandemic economic relief or stimulus legislation would have to include a five-year lawsuit shield for businesses. Drafters included the primary components of this shield in the Safe to Work Act, creating a safe harbor for businesses accused of exposing people to the coronavirus absent clear and convincing evidence of gross negligence or willful misconduct or a failure to make reasonable efforts to comply with government standards and guidance (2020). Other provisions would have tightened up causation rules (actual exposure to COVID-19 caused the injury), limitation periods, and recoverable damages. In the end, as negotiations continued in December 2020, legislators traded off the federal shield against the relief for state governments and the shield was absent from the COVID-19 Economic Relief Bill that President Trump signed. With the loss of control of the Senate by the GOP, a federal shield becomes less likely going forward. However, without a filibuster-proof majority, the new administration of President Biden may still encounter it in negotiations for further relief packages.

State shields. As noted in Volume I, mainstream liability shields such as those that gubernatorial emergency declarations triggered in workers' compensation laws and pre-COVID-19 immunities, may be applicable to some defendants. In the first months of the pandemic these were supplemented by a series of COVID-specific shields aimed at immunizing health care providers (Terry, 2020). The obvious intent behind these shields was to protect front-line health care workers and health care facilities from negligence liability. Their likely imperative was the large number of health care workers working beyond their jurisdiction of licensure and malpractice insurance or outside their scope of practice. This interpretation is consistent with the large number of northeastern states that introduced such liability shields at a time when the outbreak was concentrated there. As with most "Good Samaritan" type statutes, the immunity is lost in cases of willful, criminal, or reckless conduct.

The earliest shields were promulgated as part of gubernatorial emergency declarations. However, subsequent waivers tended to be statutory. As of the end of January 2021, 24 states have some type of liability shield applying to health care providers, split equally between executive orders and legislation (Figure 31.1).

The broadest health care liability shield in that first batch of legal protections in spring 2020 was New York's Emergency or Disaster Treatment Protection Act of 2020. Reportedly, health care provider and nursing home lobbyists drafted the legislation themselves. It explicitly immunized health care professionals and facilities, including nursing homes, home care services, and even health care facility administrators and executives. The immunity extended to "the diagnosis, prevention, or treatment of COVID-19" and "the care of any other individual who presents at a health care facility or to a health care professional during the period of the COVID-19 emergency declaration." In an apparent display of buyer's remorse, in July 2020, New York restricted the immunity to "the diagnosis or treatment of COVID-19" or "the assessment or care of an individual as it relates to COVID-19, when such individual has a confirmed or suspected case of COVID-19" (Emergency or Disaster Treatment

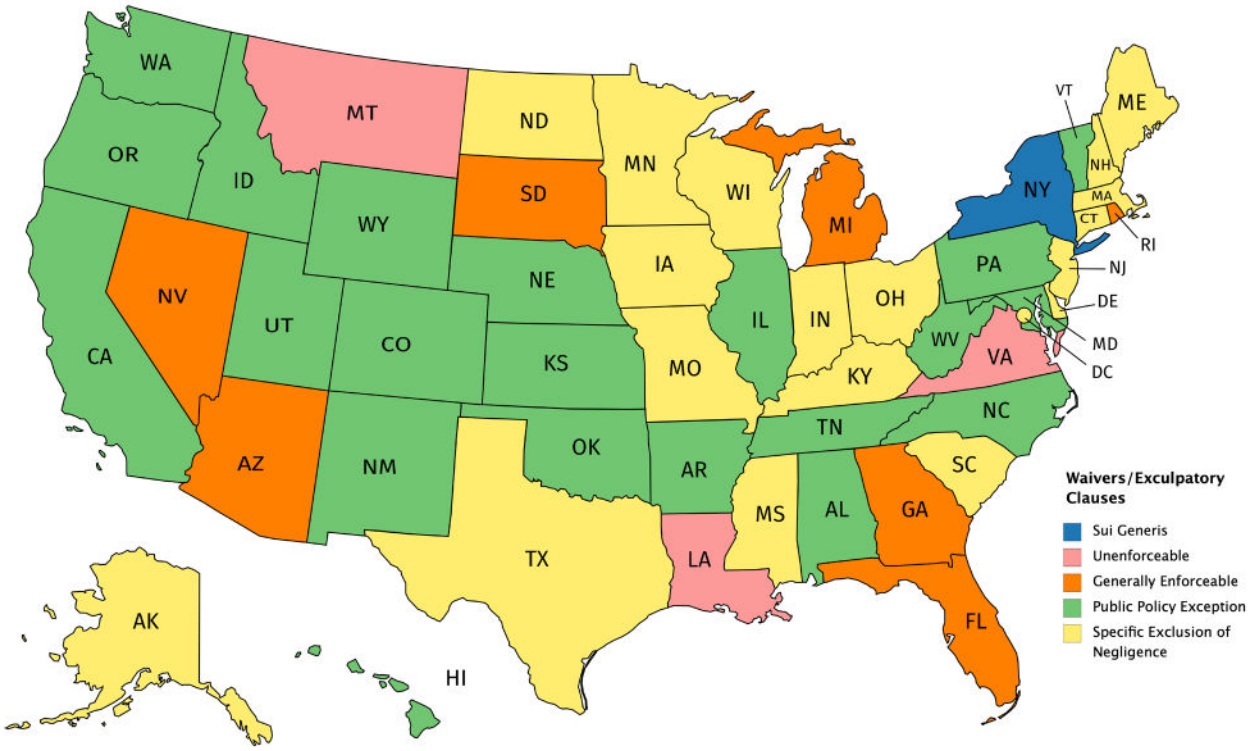


Figure 31.3

Protection Act, 2020). That reduced immunity is more consistent with that in other states that tend to tie the shield more directly to COVID-19 activities or patients.

Following the spring 2020 re-opening, there has been reduced activity with regard to health care immunity, although recently Michigan (COVID-19 Response and Reopening Liability Assurance Act, 2020) and Ohio (Ohio HB 606, 2020) enacted limited civil immunities for the health care community, and the proposed federal shield would have included health care providers.

In contrast to the slowing of immunizing activity with regard to health care providers, state legislatures continue to be active in providing immunity for businesses, ostensibly to encourage them to re-open or stay open. As of January 2021, 15 states have enacted shields by statute and two by executive order, and legislation is proceeding rapidly in two additional states (Figure 2). The northeastern states that were quick to enact provider liability shields so far have not favored this broader business immunity.

There are, of course, both narrow and broad differences between the approaches in these 19 states. For example, they vary as to their applicable dates (both as to accrual and the length of the immunity) and the definitions of the protected businesses. While it is common to include exceptions for reckless or willful conduct, there is little consistency as to the reach of the immunity. For example, the Michigan statute immunizes those who act "in compliance with all federal, state, and local statutes, rules, regulations, executive orders, and agency orders related to COVID-19" and also excuses an "isolated, de minimis deviation from strict compliance" (COVID-19 Response and Reopening Liability Assurance Act, 2020). The Tennessee statute is more direct, denying liability "unless the claimant proves by clear and convincing evidence that the person caused the loss, damage, injury, or death by an act or omission constituting gross negligence or willful misconduct. A plaintiff filing such a claim must also file a certificate that a physician has provided a signed written statement that the physician is competent to express an opinion on exposure to or contraction of COVID-19 and, upon information and belief, believes that the alleged loss, damage, injury, or death was caused by an alleged act or omission of the defendant or defendants" (Tennessee COVID-19 Recovery Act, 2020). The Ohio statute provides that, in the absence of the statutory immunity applying, class actions are still not permitted. (Ohio HB 606 §2(B), 2020).

Exculpatory clauses. In addition to lobbying for legislative relief, some businesses have begun to incorporate exculpatory clauses or waivers in their contracts or signage. News reports have noted such waivers at theme parks, political rallies, and even a bar examination.

With rare exception (for example, New York's General Obligations Law § 5-326, which provides a catalog of businesses that may or may not waive their liability) the controlling law in the states is to be found in case law. Only a very small number of states outright prohibit exculpatory clauses. What distinguishes the state jurisprudence is the doctrine courts primarily use to limit the applicability of such clauses (some may use multiple doctrines). (Figure 31.3).

A large number of jurisdictions view the primary validity issue as whether the activity involved was discretionary or recreational, as opposed to being a public or necessary one. Because this "public policy" exception is applied on a case-by-case basis and only the extremes are easy to predict (for example, hang-gliding can be waived, health care cannot), arguably, events such as political rallies or bar exams seem to fall on the side of the latter. Another approach courts take is to allow the waiving of negligence liability but not willful or reckless conduct. Debatably, a political rally that ordered the removal of social distancing signs would be acting recklessly. Finally, some courts use a procedural screen, requiring that for an exculpatory clause to be valid it has to be explicit as to the conduct it seeks to waive — negligence, for example.

At least one state has narrowed the line between liability shields and waivers. Thus, the Georgia statute creates a rebuttable presumption of the affirmative defense of assumption of risk for a health care provider or business that posts at a point of entry a sign, in at least one-inch Arial font, stating the following:

> *Warning*
>
> *Under Georgia law, there is no liability for an injury or death of an individual entering these premises if such injury or death results from the inherent risks of contracting COVID-19. You are assuming this risk by entering these premises.*

Assessment

Little has changed since the publication of Volume I that alters the assessment therein of COVID-19 liability or liability waivers. It remains understandable that, with all the safety and economic uncertainties, businesses would seek the certainty of legal immunity. Less admirable are opportunistic stakeholders with imperfect safety records seeking broad immunity for the types of acts or omissions that caused harm prior to COVID-19 (Terry, 2020). It should also be noted that liability shields are not apolitical but give state legislatures the opportunity to pass "easy" pro-business legislation while failing to address much harder questions such as supporting or calibrating mitigation policies.

Liability

It remains the case that COVID-19 lawsuits are not going to be easy to win. Viral transmission of COVID-19 remains possible even where reasonable care is taken. Further, before the pandemic some of the defendant cohorts had succeeded in blocking or reducing liability by persuading legislatures to cap damages (health care providers) or allow cases to be moved out of courts into binding arbitration (nursing homes).

Shields

Reliance on the large number of shields now in force will slow but not eliminate COVID-19 litigation. Courts may be sympathetic to constitutional complaints about statutes that differentiate between plaintiff cohorts (those injured by coronavirus infection rather than some other premises defect) and access to the courts. Consider, for example, a recent opinion of the Oregon Supreme Court overturning a legislative noneconomic damage cap as violative of the state constitution's remedy clause (*Busch v. McInnis Waste Systems, Inc.*, 2020). Also, the recklessness of some businesses and their refusal to obey occupancy limits and other mitigation efforts will pierce many shields. Then, there are the interpretative questions such as the extent to which the defendant's conduct must arise from COVID-19 emergency treatment or state ordered mitigation for a shield to apply.

Equity

Liability and liability shields raise concerns about equity and disparate impact that are difficult to calibrate. Health care providers and retail businesses face extreme economic difficulties during COVID-19. However, they are usually successful in externalizing their liability risks with liability insurance. Injured patients, nursing home residents, and business invitees have no equivalent mechanisms beyond the uncertainties surrounding their own health insurance. Equally, those businesses have proven adept at lobbying against regulation, the alternative to liability or markets to deter irresponsible conduct. In general, therefore, liability and the minimalization of shields or waivers appear to be on the side of equity. Long-term, therefore, adding "private Attorneys General" to the fight should break down disparities. Short-term, however, the question is more difficult. Large businesses such as supermarkets often close their locations in less affluent areas because of liability concerns fueling further decline. Further, while large businesses can weather the pandemic's economic impact, the same is not true of small businesses in less affluent areas that are often owned by persons of color. Unfortunately, liability laws are insufficiently nuanced to deal with these issues not least because tort law does not take into account financial resources in setting the reasonable care standard. However, liability shields could incorporate more progressive approaches, for example by limiting liability to businesses with lower turnovers.

Lessons Learned and Recommendations

Over time some states will likely begin to roll back over-protective liability shields or remove certain less-deserving cohorts such as nursing homes from their protection. In other state capitols business interests having successfully lobbied for COVID shields may be emboldened to extend or expand the shields beyond their current role. One continuing truism should govern how states should respond: responsible actors likely will operate conscientiously whatever the liability model, only bad actors need liability shields or waivers.

Recommendations for Action

Federal government:

- There is no evidence that a broad federal liability shield is necessary. Demands for such not only are unwarranted but also typify unconscionable, opportunistic behavior by industries with poor safety records.

State governments:

- Calls for broader immunity shields should be resisted, particularly where the conduct for which the shield is sought was not in mitigation of the pandemic but actually increased the transmission.
- State policymakers would better serve businesses and other stakeholders not by providing immunity from unreasonable care but by reducing uncertainty with transparent, data-driven guidance on re-opening and allowing that to inform the existing and appropriate reasonable care standard.
- States considering liability shields should exclude well-financed business that are less in need by, for example, referencing annual turnover.

Courts:

- The federal courts should narrowly interpret the PREP immunity and not extend it to failure to obtain or implement adequate countermeasures.
- State courts should carefully scrutinize the constitutionality of liability shields and not show the same deference to legislative action given to malpractice reform and interpret liability shields narrowly.
- State courts should void the exculpatory clauses being inserted into theme park and other contracts where they impact services of general public interest and emphasize that such waivers do not apply to reckless conduct.

About the Author

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COVID-19 Illustrates Need to Close the Digital Divide

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SUMMARY. As the COVID-19 pandemic continues to influence nearly every facet of daily life across the nation, individuals remain heavily reliant on internet services to access employment, job opportunities, telehealth, education, social supports, and emergency response information vital to staying safe during the COVID-19 pandemic and other natural disasters. Many educational institutions remain closed to in-person learning or require students and parents to pivot from in-person learning to distance learning as infection rates in schools and communities ebb and soar. Individuals who lack broadband access are being left behind, unable to access many of the essential services and conditions that support health and health equity. This Chapter will update information contained in Chapter 30 in ***Assessing Legal Responses to COVID-19: Volume I***; assess new data on the digital divides impacting households and communities during the COVID-19 pandemic; and discuss key legal and policy recommendations to bridge the digital divide for the long term.

Introduction

Broadband service can connect you to a wide-range of services that support healthy outcomes and health equity; however the "digital divide" keeps millions of individuals from accessing broadband at home. Access to home broadband internet service, has long been inequitable for two primary reasons: 1) affordability: households cannot afford the relatively high cost service and 2) availability: broadband infrastructure is not available in some areas of the country. FCC estimates that about 30% of urban residents, 40% of rural residents, and 55% of residents on Tribal lands do not subscribe to a home broadband service (FCC, 2020). These individuals are unable to access their classrooms, jobs and job opportunities, telehealth services, social supports, civic opportunities, and even disaster relief information from home, and no longer have reliable access to broadband at schools and libraries that have been shuttered in response to the COVID-19 pandemic (Benda, 2020).

While federal laws provide monetary incentives for private companies to build broadband infrastructure in unserved rural communities, there is no significant federal oversight over infrastructure deployment, quality of service, or prices private companies charge. Digital deserts exist in rural and urban areas where broadband service providers will not build infrastructure due to the limited number of potential residential subscribers in sparsely populated areas or low-income neighborhoods. Digital redlining can also result in substandard service or exorbitant broadband service fees in some urban areas, and federal law does not require broadband providers to offer the same level of service, or any service at all, to every household within a service area (CWA, 2020). Even where broadband infrastructure does exist, it may not be affordable for many households — at an average cost of $60/month, broadband subscriptions are increasingly out of reach for lower-income households. In fact, affordability is a significant hurdle facing many households that have access to broadband infrastructure; FCC estimates that while 94% of the U.S. population has access to fixed broadband infrastructure, only 65% subscribe to an available service (FCC, 2020). Some Tribal, state, and local governments are filling the void left by private broadband companies via programs that make broadband service more affordable, increase competition, and provide public broadband service to communities that lack reliable service from private broadband providers (Tostle, 2021).

Federal Coronavirus Aid, Relief, and Economic Security Act (CARES), Pub. L. No. 116-136, funding, and other private and public investment have helped supply broadband connections for many students and patients during the COVID-19 pandemic. Yet, the digital divide continues to restrict educational, employment, health, and civic opportunities for many individuals, primarily in low-income communities and communities of color. According to data collected via the U.S. Census Bureau's weekly Household Pulse surveys, the digital divide has not improved significantly during the pandemic and many children are still unable to access online educational resources (Ong, 2020). During the fall 2020 semester, 27% of Black households and 29% of Hispanic households with K-12 students lacked consistent access to broadband services needed to support online learning (Ong, 2020). However higher-income and white households fared better, with only 20% of white households unable to consistently access broadband services for remote learning, and only 12% of students in households with income over $100,000/year lacking reliable access to broadband (Ong, 2020).

An Update: The Digital Divide, COVID-19, and the U.S. Legal and Regulatory Response

In recent months, the federal government has provided significant funding to build broadband infrastructure in unserved rural areas, established a program to expand broadband adoption on tribal lands, and created temporary programs to reduce broadband service costs and broadband inequities that result from digital redlining and disinvestment in low-income neighborhoods and communities of color. State and local governments and school districts have also made serious efforts to address the digital divide via local laws and policies and public-private partnerships. These efforts can help bridge the digital divide during the COVID-19 pandemic and beyond.

U.S. Congress

In December 2020, as part of its Consolidated Appropriations Act of 2021, Pub. L. No. 116-260, Congress created several shorter-term programs to expand broadband infrastructure deployment, address affordability barriers underlying the digital divide, and reduce inequities in Black and Tribal communities, including:

The Emergency Broadband Benefit Program. This program provides $3.2 billion in temporary funds to reduce monthly broadband service fees by up to $50/month ($75/month for eligible households on Tribal Lands) for low-income households and households experiencing a substantial loss of income due to the COVID-19 pandemic. The program also reimburses broadband service providers $100 for internet-enabled devices sold to participating households for $10-$50. This benefit is drawn from a newly created, Emergency Broadband Connectivity Fund, and is set to expire six months after the Department of Health and Human Services public health emergency ends. The program, while not an expansion of the current Lifeline benefit program, is likely to provide additional benefits for lower-income families that are eligible for the Lifeline benefit and other families that cannot afford monthly home broadband service.

Office of Minority Broadband Initiatives. The newly formed Office of Minority Broadband Initiatives will identify opportunities to expand access to broadband service, and promote digital opportunities, connectivity, digital literacy, and broadband adoption at historically Black colleges and universities, Tribal colleges and universities, minority serving higher education institutions, and nearby income-limited anchor communities.

The Connecting Minority Communities Pilot program. This program will provide $285 million in grants to historically Black colleges and universities, Tribal colleges and universities, minority serving institutions, and consortiums between these educational institutions and minority business enterprise or tax exempt organizations in nearby income-limited anchor communities. These grants can be used to facilitate education or operate minority business enterprises or organizations. The program directs 40% of funds to historically Black colleges and universities, and 20% to educational institutions for broadband internet service or equipment for students.

The Tribal Broadband Connectivity Program. This program will distribute $1 billion in grants to Tribal governments for broadband infrastructure deployment, affordability programs to reduce costs and prevent disconnections, and programs that support remote learning, telehealth, and digital inclusion efforts.

The Consolidated Appropriations Act of 2021 also appropriates $250 million for the COVID-19 Telehealth Program created as part of the CARES Act, and $300 million for rural broadband infrastructure deployment grants.

The Federal Communications Commission

FCC recently took steps to reach its $20.4 billion pre-pandemic commitment to deploy broadband infrastructure to unserved rural communities. In December 2020, FCC announced the winners of Phase I Rural Digital Opportunity Fund program, allocating $9.23 million to extend broadband infrastructure to 5.2 million unserved rural households and businesses over the next six years (FCC, 2020). In Phase II, FCC plans to distribute an additional $11.2 billion to rural areas that are unserved or partially served via existing broadband infrastructure.

Throughout 2020, FCC encouraged broadband providers to voluntarily expand broadband service for students, patients, and low-income households, by:

- extending, until June 21, 2021, regulatory waivers that allow schools and health care institutions that participate in the FCC's E-rate and Rural Health Care programs to receive free or discounted products and services from broadband providers, including devices, services, hot spots, and home broadband services for students and patients (In re Rural Health Care Universal Service Support Mechanism, 2020).
- extending both its prohibition on de-enrollment from the Lifeline program and its waiver of some requirements that hamper newly unemployed subscribers efforts to quickly access Lifeline benefit.

While the FCC chose not to utilize its regulatory authority to expand its Lifeline or E-rate programs to make home broadband service more affordable for students or low-income households in 2020, some developments in early 2021 indicate there may be renewed focus on utilizing FCC programs to address the digital divide affecting students. In late January 2021, President Biden issued an Executive Order on Supporting the Reopening and Continuing Operation of Schools and Early Childhood Education Providers, encouraging the FCC to "to increase connectivity options for students lacking reliable home broadband, so that they can continue to learn if their schools are operating remotely." Less than a month later, FCC sought public comment on several petitions seeking emergency relief to allow the use of E-rate funds to support off-campus access to broadband services for students who lack home internet access during the COVID-19 pandemic (FCC, 2021).

State and Local Policies and Partnerships

States and local efforts have helped connect households in underserved communities and school districts during the COVID-19 pandemic and resulted in policies to address the ongoing digital divide. For example:

- the Chicago Connected program provides free home broadband service to students in the Chicago Public School District (Chandra, 2020);
- Denver residents passed Ballot Measure 2H, a referendum to opt the city out of a state law that prevents municipalities from building broadband networks;
- many states have utilized CARES funds to purchase internet-enabled devices, wireless hotspots and expand access to public Wi-Fi, telehealth, and residential broadband infrastructure (Chandra, 2020);
- and a recently adopted Arizona law, 2020 Ariz. Legis. Serv. Ch. 84 (S.B. 1460), allows local electric cooperatives to provide broadband service.

These state and local efforts to expand competition in the broadband market, make broadband more affordable, and increase broadband access via community anchor institutions and schools, will help ensure greater access to affordable broadband services now and in the future.

Lessons Learned and Legal and Policy Opportunities to Limit Public Health Inequities Stemming from the Digital Divide

The U.S. COVID-19 pandemic response has been largely premised on "staying home to stay safe." However, across the nation, individuals without home broadband service simply cannot stay home because they cannot connect to online services necessary to promote public health and health equity — including online classrooms, remote job opportunities, telehealth, government services, and emergency services. Efforts to leverage the FCC's Universal Service Fund programs to address affordability limitations underlying the digital divide; increase FCC regulatory oversight; and focus resources on state and local programs to increase competition and create local networks, can help reduce the digital divide for the long-term.

Leveraging Federal Universal Service Affordability Programs to Reduce the Digital Divide

The FCC's Universal Service Fund (USF) programs, 47 U.S.C. § 254, are meant to ensure that all households in the United States have access to, and can afford, telephone and broadband services. As the COVID-19 pandemic has eliminated opportunities to access the internet services outside the home, the FCC should leverage its USF programs to help eliminate the digital divide by making home broadband more affordable. See Assessing Legal Responses to COVID-19: Volume I for additional information on the Universal Services Fund Program, see Chapter 30. However, in 2020, FCC spent only 10% of USF funds to make broadband affordable for disconnected low-income consumers (Federal-State Joint Board, 2020). The Lifeline program is vastly underused, with only 25% of 33 million eligible households actually receiving the Lifeline benefit, and FCC disbursing only $831 million of its $2.385 billion statutorily authorized budget for Lifeline in 2020 (Federal-State Joint Board, 2020). For many low-income households, which can, on average, only afford to pay around $10/month for broadband, the $9.25 monthly Lifeline discount simply is not enough to make broadband affordable. A substantial increase in the Lifeline broadband discount — similar to the $50/month Emergency Broadband Benefit included in the 2021 Consolidated Appropriations bill, could help address racial inequities underlying the digital divide and increase participation in the program in both urban and rural communities.

FCC could likewise tackle the digital divide and educational inequity by authorizing schools and libraries to utilize USF E-rate funds to provide home broadband connections to disconnected students that are unable to access their online classrooms. Despite its reluctance to do so in 2020, FCC has previously allowed USF funds to be used to provide broadband services directly to students' and patients' homes, and FCC is currently considering 11 petitions asking for E-Rate-funds to be used for off campus broadband connections that can enable remote learning for the duration of the pandemic (FCC, 2021). If FCC does not move to authorize use of E-rate funds for this purpose, federal legislation or directed funding could be used to clarify that E-rate funds can be used to provide broadband to students' home classrooms. Such action could greatly limit digital inequities that hamper educational opportunities for millions of children in the United States and contribute to lasting educational inequities and learning loss, particularly in low-income communities and communities of color.

Home broadband service has become indispensable during the COVID-19 pandemic and FCC should leverage its USF programs to ensure all households can access classrooms, jobs and job opportunities, and telehealth services from home.

Increasing FCC's Regulatory Oversight

The COVID-19 pandemic shed new light on the ongoing debate over the level of regulatory control needed to ensure equitable access to affordable broadband service. As the pandemic aggravated public health disparities stemming from the digital divide, FCC relied on voluntary measures to limit the inequities stemming from the digital divide by:

- securing voluntary commitments from broadband service providers to waive late fees, not terminate service, and open Wi-Fi hotspots; and
- encouraging broadband service providers to provide home broadband access to schoolchildren via partnerships with schools districts.

With few regulatory options to ensure high quality, affordable service for all U.S. households during the pandemic, the FCC Chairman called on Congress to take action to ensure "doctors and patients, students and teachers, low-income families and veterans, those who have lost their jobs and livelihoods due to the pandemic and the accompanying lockdowns" remain connected (FCC News).

FCC's lack of regulatory opportunities to limit the worsening impacts of the inequitable digital divide during the COVID-19 pandemic stems from FCC's 2017 decision to release broadband providers from common carrier regulations found in Title II of the Communications Act (Holmes 2020). Common carrier regulations, which still apply to telephone service providers, provide increased regulatory oversight, require common carriers to furnish service upon reasonable request where in the public interest, and prohibit unjust or unreasonable discrimination in charging, practices, facilities and services (Gilroy, 2020). Individuals can file complaints with FCC under 47 U.S.C. § 208, alleging discrimination by common carriers (see for example *Taylor v. AT&T Corp.*, 2017).

The lack of common carrier status for broadband providers also limits the number and type of providers that can offer Lifeline discounts to broadband subscribers, and may place the program on questionable legal ground because only common carriers are eligible to receive the Lifeline reimbursement for providing discounted services (FCC Order on Remand, 2020). Digital inclusion proponents have sought reconsideration of FCC's position, and argue that eliminating the common carrier designation for broadband service providers narrows the program, limits options for Lifeline subscribers who wish to utilize a broadband only service provider, and reduces competition by limiting opportunities for broadband only providers (Common Cause, et. al, 2021).

FCC could restore common carrier status for broadband service providers by redefining broadband service as telecommunications service subject to common carrier regulations. However, courts have broadly deferred to FCC's decisions as to whether broadband is, or is not, a telecommunications services subject to common carrier regulation, finding either interpretation permissible under the federal Telecommunication Act and making it possible for a future FCC to, again, release broadband from common carrier regulations (Gilroy, 2020) To prevent weakening of FCC regulatory oversight options in the future, Congress could also enact a law clearly defining broadband service as a telecommunications service subject to common carrier regulation, or develop other oversight mechanisms that prohibit discriminatory pricing, services, and deployment. With such increased regulatory oversight, FCC could better help address the digital divide, and its disproportionate impacts on low-income households and communities of color, now and in future public health emergencies.

Public Broadband Service

Public broadband services operated by local governments, such as municipalities, Tribes, or rural electric cooperatives, can help bridge the digital divide in underserved and unserved communities by increasing availability and competition, and providing affordable broadband service. Opponents of community broadband service, citing unfair competition, taxpayer risk, and private sector disinvestment, have backed state laws restricting community broadband services via preemptive laws banning or restricting community broadband networks. FCC's efforts to eliminate these state specific restrictions have failed, however, Congressional action barring state restrictions on public broadband services could help encourage state and local action to bridge the digital divide.

Assessment

Many of the voluntary efforts urged by the FCC to keep people connected during the pandemic, while helpful, failed to ensure equal access to online services necessary to promote public health and health equity. Recent digital inclusion and affordability programs are key stepping-stones to bridging the digital divide, and should be complemented by long-term federal, state, and local policies and programs that prioritize affordable, quality broadband service for all students and households, and provide the regulatory oversight needed to ensure the digital divide does not exacerbate health inequities now, and in the future.

Recommendations for Action

Federal government:

- Congress should amend Title 47 of the United States Code, to classify broadband as a telecommunications service, or otherwise provide needed oversight that could help increase competition and eliminate the digital divide.
- Congress should amend Title 47 of the United States Code, to prohibit state preemption of local broadband markets and decision-making.
- The FCC should issue an order authorizing the use of E-rate funding to purchase home broadband connections for students; and waiving the E-rate funding penalty for schools that provide such connections. FCC should revise its regulations, 47 C.F.R. § 54.500 et seq, to codify these changes and expand the E-Rate program. If FCC fails to take should action, Congress should clarify that E-rate funding can be used to purchase home broadband connections for student's home classrooms.
- The FCC should revise its Lifeline regulations, at 47 C.F.R. § 54.400 et seq., to increase the amount of the Lifeline discount so that low-income consumers can obtain broadband service for $10 per month.

State governments:

- State legislatures should repeal state laws that prevent community broadband service providers.

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PART 6

Taking on Disparities and Protecting Equal Rights

COVID-19, Incarceration, and the Criminal Legal System

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SUMMARY. America's status as the world's leading jailor is a key factor rendering it especially vulnerable to the COVID-19 pandemic. Contact with the criminal legal system is a documented driver of health harms on both individual and community levels, with disproportionate impact on people of color. COVID-19 magnified the deleterious public health impact of policing, prisons, community supervision, and other elements of the criminal legal apparatus. On the structural level, decades of lavish spending on the United States' vast system of control and punishment has crowded out investments in public health prevention and social support infrastructure, making the nation uniquely ill-prepared to weather the COVID-19 disaster. In a tragic illustration of politics trumping science, elected officials and correctional administrators ignored calls to make rapid depopulation of correctional facilities a core component of the U.S. COVID-19 response. The number of people released remains devastatingly small, while crowded, unsanitary, and inhumane conditions persist in many facilities. Predictably, this resulted in explosive outbreaks of COVID-19 behind bars, among correctional personnel, and in surrounding communities. But it is not too late: states and the federal government can still take immediate action to protect those who remain incarcerated; chief among these steps are (1) depopulating correctional facilities to reduce the number of people held in congregate settings and (2) prioritizing people incarcerated and correctional staff for vaccine distribution. When it has occurred, depopulation of correctional settings is rarely paired with meaningful efforts to connect reentering individuals to vital supports. Community supervision systems largely failed to relax onerous probation/parole requirements. In many jurisdictions, police have taken on enforcement of physical distancing and other public health orders; a sharply disproportionate burden of which has fallen on Black, Indigenous, and other people of color. The crisis in American policing has been especially on display when misinformation-fueled protests against pandemic controls like masks and restaurant closures receive tacit — or express — support from law enforcement while protests against brutality have been met with violence. This Chapter discusses how the U.S. criminal legal system continues to shape its COVID-19 response. It (1) explains how the criminal legal system continues to exacerbate the ongoing public health emergency, and (2) focuses on ways in which the incoming Biden-Harris Administration can begin to undo the damage wrought by the outgoing federal administration through neglect and missteps. For more information on COVID-19, incarceration, and the criminal legal system, please see Chapter 31 in ***Assessing Legal Responses to COVID-19: Volume I***.

Introduction

Our first Chapter began with a breakdown of why the criminal legal system was a public health crisis before COVID-19. The United States leads the world in the number of people it incarcerates and oversees through its criminal legal system; in this vast regime of control and punishment, people of color are grossly overrepresented. Moreover, mental health, addiction, and poverty play an overwhelming role in a person's chances of incarceration. Thus, structural racism and economic inequality, combined with overcriminalization and disinvestment in health and social supports, has resulted in more than three million people behind bars and more than 6.5 million people living under correctional supervision —including probation and parole — comprising 6% of the adult population (Macmadu et al., 2020). This vast criminal legal system has also diverted investments in public health prevention and social support infrastructure, aggravating the vulnerability of many to criminal legal contact.

The Criminal Legal System in the Context of COVID-19

Even before the world understood the magnitude of the catastrophe COVID-19 would wreak on our society, economy, and population, the United States was in the midst of a separate crisis

of over-incarceration. As public health experts noted in a letter to incoming Biden-Harris COVID-19 Advisory Board members, despite nationwide crime rates falling for decades, the incarcerated population expanded 300% between 1980 and 2008 and declined by just 8% since 2008 (Franco-Paredes, 2020). Black, Indigenous, and other people of color continue to be overrepresented in the criminal legal system, and the aging population in correctional facilities further contributes to the risk COVID-19 presents to people incarcerated.

One important factor undercutting health care in correctional facilities is the prohibition on Medicare or Medicaid reimbursement for correctional health services. This exclusion — referred to as the "inmate exception" — contributes to significant under-resourcing and has produced an isolated correctional medical system that does not have to meet accreditation or other quality control mandates (Fiscella et al., 2017). The inmate exception contributes both to declines in overall health of incarcerated persons, as well as shields jails and prisons from broader regulatory and norm-setting forces that could, for example, encourage facilities to implement COVID-19-related policies to curb the spread of infection behind bars and upon release (Fiscella et al., 2020).

Disparities in COVID-19 Rates in Jails and Prisons

We now know that the rate of COVID-19 infections is four times the national rate and the mortality rate in correctional facilities is *double* that of the general population (Franco-Paredes, 2020). These figures are more troubling when broken down by state: More than 40% of people incarcerated in Arkansas, Kansas, and South Dakota were infected, and death rates in Arkansas, Delaware, Ohio, Oklahoma, and Oregon were more than seven times higher than that of the general population (Schnepel, 2020).

One report found that around 12 of every 100 individuals in state and federal prisons had recovered from or was currently infected with COVID-19 as of mid-November 2020 (Brennan Center, 2020). The raw numbers are staggering. Of the more than 330,000 people known to have tested positive behind bars, 1,968 perished (The COVID Prison Project, 2021). Moreover, those who are incarcerated have higher rates of acute and chronic health conditions than the general population, including HIV and other infectious diseases, mental health conditions, and other comorbidities — e.g., hypertension, diabetes, and asthma — directly linked to severe COVID-19-related illness and death (APHA, 2020).

The racial gradient, as surmised from limited data, is devastating, as disparities in incarceration are reflected in infection rates. Indeed, one study found that infection rates and suspected infection rates for Black Americans behind bars were anywhere from two to four times that of white individuals (Nelson & Kaminsky, 2020). Coupled with higher rates of preexisting conditions and other comorbidities, COVID-19 presents an even greater risk to people of color in both communities and the criminal legal system.

We previously outlined why correctional facilities are structurally prone to be hotspots for disease transmission. These factors include widespread overcrowding, lack of basic sanitation, substandard health care, and many other issues symptomatic of abuse and neglect of people behind bars. Moreover, confined conditions, high turnover rates, and underinvestment in resources for infection control exacerbate transmission risks in correctional facilities (Macmadu et al., 2020).

The continued lack of consistent and frequent testing, basic sanitization and hygiene products, and facility space to enable quarantining further contributes to rampant infections. Such settings led to more than 40 of the 50 largest clustered outbreaks, or "hotspots," occurring in jails and prisons (Macmadu et al., 2020). Indeed, more than 800 hotspots were in correctional facilities as of mid-November 2020, and nearly 15% of the facilities had more than 500 cases (Schnepel, 2020). Prisons and jails have long been known to be porous with respect to their surrounding communities, and COVID-19 easily breaks in and out of their walls. A prime example is Cook County Jail in Chicago, where nearly 16% of all COVID-19 cases in the state were linked to an outbreak in the facility (Macmadu et al., 2020). Importantly, those incarcerated are not the only people at greater risk in the criminal legal system: As of January 8, 2021, a little more than 77,000 correctional staff tested positive and 113 have died (The COVID Prison Project, 2021).

The overincarceration crisis has therefore — predictably — amplified the COVID-19 crisis. The dismal health status of its enormous correctional population and the failure to provide adequate reentry supports help explain the link between the United States' status as the world's leading jailer and its position at the bottom of public health rankings among peer nations. In addition to the racial justice, fiscal stewardship, and other reform imperatives, public health data demonstrating individual and community detriment from incarceration helped amplify calls for reform; however, aside from marginal sentencing reform, these calls went largely unheeded. With few exceptions, federal, state, and local governments have failed to implement meaningful policies to combat the rising number of cases behind bars.

Federal and State Failures to Depopulate Prisons and Jails

Despite the dire pre-pandemic environment and a vast body of evidence showing the particular risks correctional facilities posed to COVID-19 transmission, early calls to depopulate correctional institutions went largely unheeded. Depopulating, or "decarceration," refers to both reducing the number of people behind bars by both releasing individuals before their sentence is entirely served, and diverting individuals who would be incarcerated (NASEM, 2020). As to the latter, diversion strategies include reducing the number of arrests, eliminating cash bail and otherwise reducing pre-trial detention, and relaxing parole and probation conditions to ensure individuals remain in their communities.

During the pandemic, multiple decarceration efforts across jails, prisons, and detention centers have been undertaken, leading to an approximately 11% reduction in incarcerated populations — a drop in the bucket considering the systemic overcrowding in

correctional facilities and despite the fact that decarceration provides positive effects both for those behind bars and for people living in surrounding communities (NASEM, 2020).

Federal response. The federal response was largely characterized by confusing, often changing, guidelines for COVID-19 protocols and compassionate release for those most vulnerable to the virus. One study found that, while 10,940 federal prisoners applied for compassionate release in the first three months of the pandemic, wardens approved only 156 of those petitions, or less than 2% (Brennan Center, 2020).

Even more disturbing is the COVID-19 outbreak linked to an acceleration of federal executions by the Trump Administration over the summer when a federal Bureau of Prisons (BOP) staff member who was involved in the first execution tested positive for the virus; nevertheless, BOP neither tested everyone in the facility nor required staff to quarantine for a full two weeks, instead allowing staff to return to work after 10 days without retesting (Brennan Center, 2020).

State responses. Some states and local governments are doing slightly better with efforts to decarcerate, but by and large have failed to decarcerate at a meaningful pace even as infection rates grow (Brennan Center, 2020). New Jersey has been held up as a model for other states, expecting to reduce the state's prison population by almost 35% by March 2021 based on a recently enacted law crediting individuals with early-release credits for time served during the pandemic (Tully, 2020).

The District of Columbia enacted a similar law that both retroactively awarded good time credit for those who had served at least 20 years and enabled such individuals to cite age, health, or other 'extraordinary and compelling circumstances' as justification for early release — unfortunately, judges have rejected around 68% of such requests (Marimow, 2020).

Importantly, neither federal nor state governments are prioritizing the release of individuals particularly vulnerable to COVID-19. In California, only 62 of the 6,500 eligible individuals were released solely due to their medical conditions; the rest of the more than 7,500 people released had less than a year to serve on their sentences (Lyons, 2020).

Key Agenda Items

We previously focused on the structural components of the criminal legal system that led to the current COVID-19 crisis in carceral facilities. In this updated version of the Chapter, we take advantage of the opportunity presented by an incoming federal administration to outline actions that can address the ongoing pandemic following the disastrous failures of their predecessors.

Decarceration is Imperative to Slowing the Spread of COVID-19

As previously discussed, public health experts and criminal justice advocates have issued increasingly urgent calls for the United States to ramp up decarceration. It is not too late to embrace decarceration as both a public health and moral imperative. Resistance to decarceration is largely due to fears that releasing people present a threat to public safety, a false narrative that perpetuates irrational and outdated fears of those who are incarcerated. This, despite the fact that there exists abundant criminological evidence that releasing many incarcerated people would not pose a threat to public safety (Franco-Paredes, 2020). Examples of states that simultaneously reduced prison populations and saw crime rates decrease include California, Michigan, New Jersey, New York, and Texas (APHA, 2020).

Decarceration is the most effective way to ensure fewer people are infected behind bars, but simply releasing individuals from incarceration will not curb new infections if not paired with meaningful reentry supports. Reentry planning is essential to breaking the cycle of interaction with the criminal legal system. This includes discharge planning similar to hospitals and "warm hand-offs" (transporting person directly to services that increase positive outcomes). COVID-19 poses additional challenges: during the pandemic, reentry must not only be managed remotely, but also unequivocally include housing, transportation, and financial assistance, as well as community interventions to ensure the cycle of incarceration is broken. Such interventions should also include specialized, potentially remote, community supervision (i.e., for people with substance use disorder (SUD)); continued treatment of physical (including COVID-19) and mental health conditions; and expanded access to services. Moreover, and as discussed in our previous Chapter, releases must be sensitive to the barriers to reentry that are specifically exacerbated by COVID-19.

It bears repeating that Black, Indigenous, and other people of color are disproportionately represented in prison and jail populations. Because of this, corrections facilities and policy makers alike must ensure that pandemic-related decarceration is not racially imbalanced by, for example, taking into account the heightened risk COVID-19 presents to people of color. Corrections facilities must also immediately begin tracking and reporting data on infections and deaths, including racial and ethnic markers, if they are not doing so already.

Strategies to Protect Those Who Remain Behind Bars

We recognize that, while not every person behind bars will be eligible for early release even under the most liberal federal and state policies, correctional facilities must take meaningful action to ensure those who remain behind bars are protected from COVID-19 to the greatest extent possible.

First, this means significant investment in enhanced sanitation measures. One study found that there continues to be "shortage[s] of cleaning supplies, wipes, hand sanitizer, and even disposable covers for thermometers, and this interfered with [corrections staff] ability to conduct temperature screening among inmates" (Nelson & Kaminsky, 2020). Greater access to personal protective equipment (PPE), including masks, is imperative.

Second, there must be more frequent and robust control measures for stemming the spread of COVID-19. This includes testing of both people incarcerated and correctional staff, as well as contact-tracing. Moreover, correctional facilities must enable

more effective social distancing and quarantining capacity. Social distancing and quarantining is impossible while correctional populations remain as high as they are — this is why decarceration is so important. Absent significant reductions in the incarcerated population, however, correctional facilities must immediately institute regular testing. Those who test positive must be provided ethical quarantine spaces and their contacts traced to ensure facilities know exactly who is at further risk of contracting the virus.

Third, Congress should eliminate the inmate exception preventing Medicare and Medicaid dollars from being spent in correctional facilities. The prohibition prevents good health care in general for people incarcerated, but also prevents spending on COVID-19-related health care in the criminal legal system. Poverty is a key indicator of whether a person comes into contact with the criminal legal system, and the ban on granting those behind bars coverage under the nation's health care program for the economically disadvantaged is counterproductive and contrary to the programs' stated missions.

Lastly, and perhaps most controversially, governments must prioritize corrections staff and those incarcerated for vaccine distribution along with health care workers and other people who live in congregate settings. People behind bars should be at the front of the line precisely for the reasons detailed above. Simply put, preventing infections behind bars benefits both those inside and outside of correctional facilities. Prisons and jails are vectors for viral spread because those incarcerated cannot adequately engage in social distancing, have little access to masks and other PPE, and are exposed to countless individuals that come in and out of facilities, including staff and visitors. Despite these clear facts, governors and members of the community are hesitant to make vaccine distribution in correctional facilities a priority — this reticence will cost lives, both behind bars and in the surrounding communities.

Structural and Administrative Steps to Address the Incarceration Crisis

Finally, as previously described, the pandemic provides federal, state, and local governments the opportunity to begin to address the overincarceration crisis. This means governments should immediately begin investing in communities and alternatives to the criminal legal system, which should include access to basic resources like education, jobs, and housing, as well as affordable and accessible health care — including mental health care and substance use disorder treatment — to ensure vulnerable individuals are not funneled into the criminal legal system (APHA, 2020). Front-end solutions reduce the number of people who are ultimately incarcerated for crimes often associated with poverty, mental health conditions, and SUD. A renewed focus on racial equity could reduce racial disparities in the criminal legal system.

Similarly, governments must stop practices like pre-trial detention and cash bail that further bloat the criminal legal system and contribute to disease transmission. Changes to policing and releases from correctional facilities are estimated to prevent 23,000 COVID-19 infections among people incarcerated and 76,000 infections in surrounding communities (APHA, 2020).

In the context of decarceration, correctional facilities should move those with mental health conditions and SUD from locked facilities to community-based treatment, employing community-based interventions (see the Sequential Intercept Model section in Chapter 31 of Volume I). Legislatures must actively work to decriminalize sex work, substance use, homelessness, and other "quality of life" charges (APHA, 2020). Legislatures could also broaden public health officials' authority over correctional facilities to minimize the public health harms posed by these facilities both in the context of COVID-19 and beyond (APHA, 2020).

Finally, governments should urge and, in some cases, order correctional facilities to immediately implement policies and operating procedures to promote COVID-19-safe release. This necessarily includes better data tracking of active infections, deaths, and contact tracing but extends to ramping up post-release supports for those reentering. Moreover, facilities must have appropriate administrative capacity to ensure people do not die behind bars because staff cannot coordinate timely release.

Recommendations for Action

Federal government:

In addition to the recommendations detailed in our first Chapter, many of which have not been implemented across the board or at all, the federal government should implement the following recommendations:

- The Centers for Disease Control and Prevention (CDC) should explicitly recognize and include decarceration and expanded access to health care for incarcerated and recently released individuals as necessary guidance for federal, state, and local officials. Although a flurry of recent executive orders discussed the need for decarceration (e.g., Executive Order 14006, which directs Executive Branch agencies to end contracts with privately operated criminal detention facilities to decrease incarceration levels) ending contracts with for-profit facilities does nothing to reduce the number of people incarcerated today.
- Department of Justice leaders should utilize existing authorities, such as compassionate release and home confinement, to expedite the immediate release or transfer of elderly and medically vulnerable people out of the Bureau of Prisons (BOP). In accordance with recent Executive Orders directing executive agencies to implement policies that enhance racial equity, the Executive Branch should direct BOP to ensure that pandemic-related decarceration is not racially imbalanced.
- Congress and the Executive Branch should support COVID-19 relief funding for state, local, and Tribal criminal legal systems to incentivize a significant reduction of incarcerated populations and to assist reentry and community-based organizations to respond to COVID-19.
- The Executive Branch should direct the Attorney General to minimize arrests, decline to seek detention of individuals at their initial appearance in court, and consent to the release of those already detained, absent clear and convincing evidence that the person poses a specific threat of violence to a specific person.
- BOP should implement universal and regularly repeated testing for all correctional staff and people incarcerated. Executive Order 13996 addresses this recommendation but must be fully implemented to ensure people incarcerated and working in federal correctional facilities are tested and should go further in prioritizing these populations – those incarcerated and correctional staff – in vaccine distribution.
- Congress should pass the COVID-19 in Corrections Data Transparency Act, which requires the BOP, U.S. Marshals Service, and state and local correctional agencies to report disaggregated data to the CDC on the effects of COVID-19 in their facilities, including any racially or ethnically disparate impacts. Executive Orders 13994 and 13995 address expanding data collection, but a federal law passed by Congress to this end would better ensure COVID-19 data reporting on the state and local level.
- Congress should pass legislation using the power of the purse to incentivize states to decarcerate and provide vaccines to people behind bars, and legislation repealing the inmate exception for Medicare and Medicaid.

State governments:

In addition to the recommendations detailed in our first Chapter, many of which have not been implemented across the board or at all, state governments should implement the following recommendations:

- State prosecutors, by exercising their prosecutorial discretion, and law makers, by implementing sensible legislation, should stop practices like pre-trial detention and cash bail that further bloat the criminal legal system, as well as work to enact legislation decriminalizing sex work, substance use, housing insecurity and homelessness, and other "quality of life" charges.
- Legislators should require prisons and jails to implement policies to address COVID-19 behind bars, and to frequently report data on infections, deaths, and releases that include demographics.
- Legislators, governors, and public health departments should prioritize people behind bars and correctional staff for vaccine distributions and greatly expand compassionate release programs for the medically vulnerable.
- State prosecutors and governors should not stand in the way of requests for early release or oppose recommendations for release made by parole boards.

Recommendations continued, local governments:

In addition to the recommendations detailed in our first Chapter, many of which have not been implemented across the board or at all, local governments should implement the following recommendations:

- Local prosecutors, by exercising their prosecutorial discretion, and law makers, by implementing sensible legislation, should stop practices like pre-trial detention and cash bail that further bloat the criminal legal system, as well as work to enact legislation decriminalizing sex work, substance use, housing insecurity and homelessness, and other "quality of life" charges.
- Legislators should require prisons and jails to implement policies to address COVID-19 behind bars, and to frequently report data on infections, deaths, and releases that include demographics.
- Legislators and public health departments should prioritize people behind bars and correctional officers for vaccine distributions and greatly expand compassionate release programs for the medically vulnerable.

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Supporting LGBT Communities in the COVID-19 Pandemic

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SUMMARY. LGBT individuals suffer disproportionately in the COVID-19 pandemic. They are likely to be exposed to COVID-19 in greater numbers and suffer to a greater degree if they contract the disease. They are more likely to lose access to essential medical services, including gender confirmation and HIV medications. They are likely to suffer economic harms to a greater degree, since they are more likely to work in industries with exposure too, and likely to close because of COVID-19. They also are more likely to experience mental and emotional harms arising from the isolation, or sheltering-in-place COVID-19 necessitates. Such isolation often occurs with hostile or violent family members, while LGBT safe-spaces, organizations, institutions, and events, such as LGBT pride and LGBT centers are shut down or go virtual. This can take a toll on physical, emotional, and mental health, especially for youth and elderly LGBT individuals. Finally, when LGBT individuals seek assistance from elsewhere, including through social services, homeless shelters, and welfare, they often suffer discrimination. All these harms fall even more disproportionally on LGBT people of color and transgender individuals. To combat these harms, policymakers must implement stringent antidiscrimination protections and policies that cover the needs of LGBT individuals such as access to certain medical services. But more importantly, they should ensure that the LGBT organizations providing these services in a safe space remain funded and open. They should also collect data on the LGBT community. This Chapter is reprinted from the August 2020 edition.

Introduction

As Michelle Bachelet, the UN High Commissioner for Human Rights, has acknowledged, "LGBTI people are among the most vulnerable and marginalized in many societies, and among those most at risk from COVID-19." The pandemic has widened existing inequity in society and the LGBT community is no exception.

The harms that LGBT individuals will experience as a result of the COVID-19 pandemic fall into several categories: (1) First, there are COVID-related health harms. There is reason to believe that LGBT individuals face higher morbidity and mortality risk from the pandemic. (2) Other medical harms including lack of access to necessary medical services such as gender confirmation or HIV treatment during the pandemic. (3) Mental and emotional health harms arising from the isolation, or sheltering-in-place COVID-19 necessitates. Such isolation often occurs with hostile or violent family members. This can take a toll on physical, emotional, and mental health, especially for youth and elderly LGBT individuals. (4) Economic insecurity, given that LGBT individuals are more likely to work in industries with exposure too, and likely to close because of COVID-19. (5) Discrimination in employment and access to social services. Finally, (6) lack of community support as LGBT community organizations founder and close.

Each of these harms reinforce each other. Health harms can cause job loss and economic insecurity, and vice versa. Mental health and addiction burdens can take a toll on physical health, and render LGBT individuals ineligible for social services and welfare, which worsens these harms.

Next, this Chapter considers the increased harms that LGBT minorities—people of color and transgender individuals, face along all these axes. It concludes by considering solutions, and explaining why an inclusive approach to the LGBT experience can be a valuable tool in the broader fight against COVID-19.

COVID Related Health Issues

Experts have suggested that LGBT individuals might face higher risks if they contract COVID-19. As numerous LGBT organizations explained in an open letter, LGBT individuals have underlying health problems at higher rates than the general population that can magnify the risk of COVID-19. For example, they use tobacco, and also have asthma, at rates 50% higher than the general population, which might increase their vulnerability to respiratory conditions such as COVID-19. The community also has much higher rates of HIV and cancer, which can leave some LGBT individuals immunocompromised and vulnerable to COVID-19. While research is limited, people living with HIV are more likely

to have cardiovascular and chronic lung diseases that increase their vulnerability. These concerns are compounded for minority groups—for example, half of all black cisgender men who have sex with men (MSMs) and half of transgender women will be diagnosed with HIV in their lifetime. Finally, as discussed later in this Chapter, LGBT individuals are more likely to face economic insecurity and homelessness, which increases their exposure and vulnerability to COVID-19.

If they contract COVID-19, LGBT individuals are more likely to face barriers to receiving health care. Discrimination in health care settings remains high, and numerous LGBT individuals report avoiding health care settings except in emergency situations. Further, rates of insurance coverage are lower: 17% of LGBTQ adults do not have any kind of health insurance coverage, compared to 12% of non-LGBTQ adults (Whittington et al., 2020). Indeed, transgender individuals who face barriers to accessing bathrooms that match their gender in workplaces and elsewhere might even be unable to wash their hands to reduce COVID-19 risk (Hensley-Clancy, 2020).

LGBT individuals may also experience medical events at higher rates than the rest of the population. Transgender individuals may need access to gender confirming medication. People living with HIV need access to lifesaving drugs that they must take on a daily basis. COVID-19 has limited access to these services. For example, the Johns Hopkins Center for Transgender Health has postponed gender-affirming surgeries, and "has a moratorium on new patient intakes due to the retasking of personnel and resources to the COVID-19 response." Similarly, as I learned in an interview with the Chief of Staff of the Los Angeles LGBT Center, one of the nation's largest providers of LGBT health services in the nation, their clients feared loss of access to medication and other services. Crowding as individuals try to access these resources can increase risk for COVID-19.

LGBT individuals have among the highest rates of suicidality and substance abuse, with 40% of transgender individuals attempting suicide at some point in their lives, and LGBT youth attempting suicide at three times the rate of heterosexual youth. Similarly, LGBT adolescents are nearly twice as likely as their non-LGBT peers to have used some kind of illicit substance. Isolation and lack of supportive surroundings are linked to suicidality and relapses, or increased substance abuse (The Fenway Institute, 2020).

Such issues are particularly pronounced among certain subpopulations. First, LGBT youth often lack access to supportive surroundings. Research suggests that only a third of LGBT youth have accepting parents, and an additional third experience outright rejection, which increases suicide risk and depression exponentially (The Trevor Project, 2020). With shelter-in-place orders, CBS News reports, LGBT youth find themselves isolated at home—or what one interviewee called a "war zone." Some experience death threats. Unsurprisingly, NPR reports that the Trevor Project, a suicide prevention organization for LGBTQ youth, has seen in some cases twice the level of outreach to the organization during the pandemic than earlier in 2020.

Particularly problematic is the inability of students to access supportive resources outside the home. Schools provide material resources: 30% of youth in foster care, and 40% of homeless youth identify as LGBT. School closures mean limited access to food and other resources (Whittington et al., 2020). Although less than half of schools nationwide have organizations dedicated to supporting LGBT youth, school closures might also mean that students are unable to access those resources. University closures can present even more urgent situations, with some students forced to return to homes with which they may have cut ties, or to families that continue to misgender them—for example, referring to male transgender children as female. One student tells a reporter how "her parents call her by the wrong name, use the wrong pronouns." Apart from being cut off from support, LGBT youth may not be able to safely access transition or HIV related medication when living with their parents (Hensley-Clancy, 2020).

Older LGBT individuals face similar issues. Even before COVID-19 struck, LGBT individuals 50 years of age and older were twice as likely to live alone than their straight counterparts, half as likely to have significant others or close relatives, and four times less likely to have children; almost one quarter had no one to call in the case of an emergency (SAGE USA, 2020). Further, this population is more likely to experience health concerns, including diabetes, asthma, heart disease, HIV, cancer, hypertension, and disabilities (SAGE USA, 2020). LGBT older people are far more likely to rely on "chosen" family—close friend groups—for help. But since they do not live with these individuals, and close friends are likely to age at the same rate, such reliance can be of limited help during COVID-19's spread. And, laws such as the Family Medical Leave Act do not allow elders' chosen family to take time off to care for them if they were to become sick (SAGE USA, 2020).

Finally, even among the rest of the LGBT community, the isolation that COVID-19 necessitates can lead to harms. While 35% of straight women experience rape, physical violence, or stalking by an intimate partner, the number rises to 44% of lesbians and 61% of bisexual women. Similarly, 54% of transgender and non-binary respondents experience intimate partner violence in their lifetimes. Further, as the next Section describes, because of higher rates of poverty and stigma, and limited access to health insurance, many LGBT individuals—whether youth, elderly, or others, are unable to leave toxic home environments (Human Rights Campaign Foundation, 2020a). The isolation that COVID-19 requires thereby exacerbates severe harms that LGBT individuals experience at home.

Economic Issues

Health harms can reinforce the economic harms that LGBT individuals face. As the premier research organization on LGBT issues, the Williams Institute, and a lead advocacy non-profit for LGBT equality, the Human Rights Campaign, have emphasized, "LGBTQ Americans are more likely than the general population to live in poverty and lack access to adequate medical care, paid medical leave, and basic necessities during the pandemic" (Whittington et al., 2020). The poverty rate among LGBT individuals

is 22%, compared to 16% among non-LGBT individuals. Further, one in five LGBTQ adults have not seen a doctor when needed for financial reasons.

Against this background, COVID-19 has struck the community hard. LGBT individuals are overrepresented in industries that result in high exposure to the coronavirus. Further, many of these industries are most likely to be shut down as a result of the pandemic, increasing unemployment in the community. Research shows that the top five industries in which LGBT individuals work—comprising 40% of LGBT employment—are hospitals, restaurants and food services, K-12 education, colleges and universities, and retail (Whittington et al., 2020). By contrast, only 22% of non-LGBT individuals work in these industries. Even with short term economic stimulus, the stress on these industries means that LGBT individuals may face long-term unemployment.

Discrimination

LGBT individuals face discrimination in the workplace. In 2018, the Human Rights Campaign found that nearly half of all LGBT workers remain closeted at work. And, only about half of straight/cisgender employees reported they would be "very comfortable" with an LGBT coworker. A recent Supreme Court ruling has held that LGBT employees are protected from discrimination under federal law. But employment discrimination protections are hard to apply if the employer is not open about the reasons for the negative employment action. Further, commenters believe that the Court will hold that at least some employers can discriminate against LGBT individuals for religious reasons. Loss of employment can increase the economic and medical harms that LGBT individuals face.

COVID-19 work-from-home practices have had a mixed effect on LGBT individuals, particularly transgender individuals. Some transgender individuals report relief because teleworking allows them to use their bathroom at home, rather than worry about whether they can use their bathroom of choice at work. But others complain that Zoom is connected to their emails, and therefore uses their "deadnames," that is, names assigned to them at birth that misgender them. Further, doing business by phone rather than in person also means that some transgender individuals are misgendered as their conversation partner must rely on their voice rather than their appearance (Hensley-Clancy, 2020).

Because of the high degree of economic harms and homelessness LGBT individuals face because of familial rejection and violence, they also rely on government services such as shelters and welfare programs. LGBTQ shelters have reported a significant increases in intake—one D.C. shelter reported a tripling of intake in the first month of the pandemic. But as shelters have to engage in social distancing, many have reduced capacity, leaving LGBT individuals homeless, or only able to go to shelters that engage in discriminatory practices (Velasco & Langness, 2020).

Further, numerous Trump administration agencies have rescinded rules that prevent anti-LGBT discrimination across a range of programs, including shelters, access to healthcare, access to services funded by federal healthcare grants, and the like (Velasco & Langness, 2020). Faith-based service providers, including medical service providers, have claimed religious exemptions to discriminate against same-sex couples. This has involved situations where medical institutions have refused to provide information to same-sex spouses (Goldberg & Wechsler, 2020). Such religious entities might also engage in COVID-19 related care. For example, a field-hospital in New York requested "Christian volunteers," who would adhere to its Statement of Faith, which explicitly rejected transgender individuals and marriage equality, as NBC reports.

Loss of Community Support

LGBT individuals are facing a loss of community support due to COVID-19. The year has seen the endangering of prominent LGBT institutions: the oldest running gay bar in San Francisco has shut down, the country's third oldest LGBT newspaper is close to closing its doors, and indeed, LGBT pride celebrations around the country were cancelled or held online.

These consequences might seem trivial to outside observers, but are of vital importance to the LGBT community. As one commentator eloquently put it in the Atlantic, "queer gatherings are a rejection of queer isolation: of hiding in the closet, of believing oneself to be alone in one's identity, of fearing that embracing one's truth would result in physical harm" (Kornhaber, 2020). Unlike other communities, LGBT individuals must seek out LGBT gathering spaces, such as bars and community support groups, rather than rely on families. Sometimes, this has resulted in LGBT individuals taking risks that have led to contracting COVID-19 and death (Kornhaber, 2020).

With the cancelling of pride celebrations in particular, members of the LGBT community have expressed loneliness. Further, pride celebrations are often key for LGBT organizations to survive. The Center on Colfax—Denver's LGBT Center—forfeited around $1 million from being unable to produce PrideFest—which it would have used to support mental health and legal services. Cummings from the Los Angeles Center, which also provides medical care, housing, and other services, explained that funding sources have dried up, as organizations do not realize the COVID-19 related support these organizations provide. This will further endanger the support that it can provide for the community.

Harms to Subpopulations

The harms arising from COVID-19 fall disproportionately on LGBT individuals of color and transgender individuals as the figure below lays out. While the figure focuses on economic disparities arising from COVID-19, these disparities appear in other areas. For example, while 12% and 17% of the general population and the LGBT community respectively lack health insurance, those figures jump higher to 22% for transgender individuals, and 32% for transgender individuals of color. This increases their exposure to COVID-19 and secondary harms as laid out above.

Solutions

Solutions should be adopted at three levels. First, the Trump administration's decisions to repeal antidiscrimination protections for the LGBT community should be reversed. Indeed, the Supreme

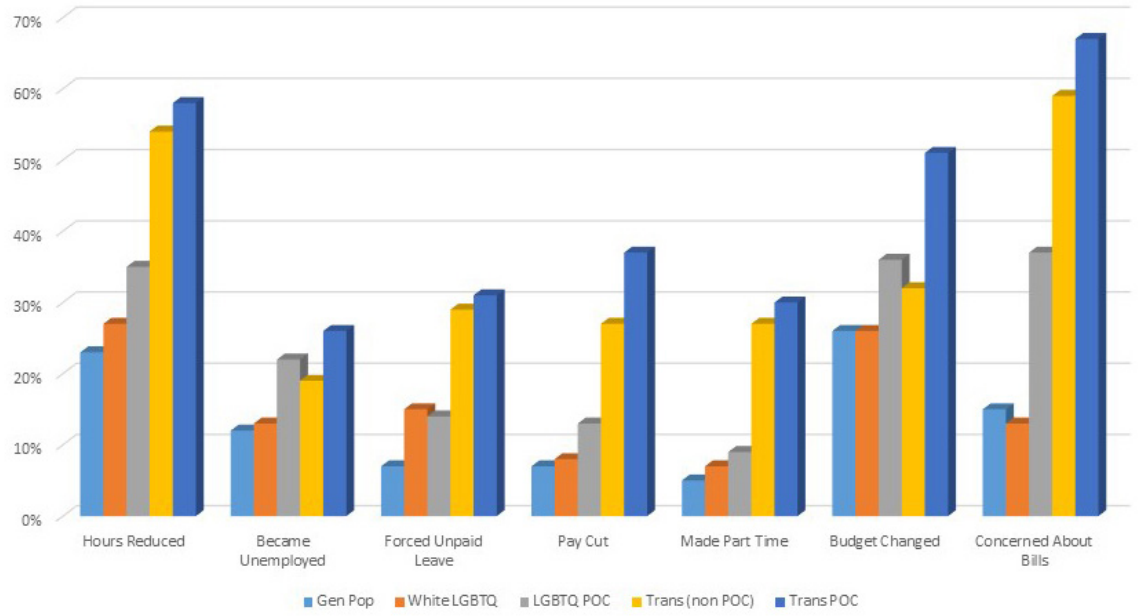

Figure 34.1: Effects of COVID-19 on LGBT Subpopulations. Source Human Rights Campaign Foundation (2020b and 2020c).

Court recently held that discrimination based on transgender status (that is, not conforming to the sex one is assigned by birth) and on sexual orientation (that is, discriminating based on the sex to which an individual is attracted) were both forms of prohibited sex discrimination. While the Court limited its holding to the employment context, its reasoning extends more broadly. For example, the Affordable Care and Fair Housing Acts prohibit sex discrimination in medical contexts and shelters respectively. Agencies must recognize this legal change promptly, and Congress should exercise its oversight power to make sure that they do so.

Secondly, states and federal entities should provide assistance targeted towards LGBT individuals and organizations that are foundering at this time. Assisting LGBT organizations is vital for a group of individuals who may lack familial support. Importantly, LGBT organizations may lack access to paycheck protection program funding, and do not get access to funding directed to organizations providing COVID-19 support. But LGBT individuals are most likely to get supportive and non-discriminatory care at these LGBT organizations, and thus are likely to go to these organizations for relief. These organizations have historically provided gathering places for LGBT youth and elders; they should be well-resourced as they shift to changing the way in which they provide services. Rather than try to reinvent the wheel, policymakers should deputize these organizations for providing community services.

Targeted assistance should also involve data collection on LGBT individuals at times of COVID-19 testing, and in providing other services, so that we can better understand community needs. So far, Pennsylvania is the only state to require such testing. Similar legislation is expected to pass in California. Other states and the federal government should take similar steps. (Lang, 2020).

Further, the government should provide advice and services with an eye to LGBT individuals. For example, state and local governments should ensure that HIV testing and gender confirmation treatment remain available even during times of shelter-at-home. Further, they should not require identification for accessing services, as transgender individuals might have identification that misgenders them, and does not conform to their appearance, which may result in a denial of services.

Third, given the economically precarious state of LGBT individuals, measures that would provide assistance to vulnerable communities in general, including medical, food, and shelter assistance, as detailed elsewhere in this report, would help LGBT individuals as well (Gruberg, 2020).

Conclusion

LGBT individuals have been more likely to take steps to limit the spread of COVID—for example, 54% of the community is avoiding public transportation, 53% have purchased masks, and 27% have spoken to a doctor about the virus, compared to 44%, 43%, and 14% of the general population respectively (Human Rights Campaign Foundation, 2020d).

We should now take steps to actively support and include the community. An inclusive approach can help control COVID-19 more generally. For example, in light of blood shortages caused by the crisis, the FDA took steps to limit its rule that prohibited most MSM from giving blood. But MSM remain excluded if they have had a sexual encounter with any other man in the previous three months. Apart from imposing stigma on members of the LGBT community, such a ban harms the COVID-19 relief effort. Similarly, discrimination in healthcare settings makes it less likely that LGBT individuals will go in for testing, or if they do, that they will candidly engage in discussions regarding contact tracing that may out them to providers who do not know they are LGBT.

Members of the LGBT community survived the AIDS epidemic by relying on each other, by using protection to protect each other, and by taking community action without relying on the federal government. Drawing from these community norms by adopting LGBT-inclusive policies can teach us ways to bring COVID-19 under control as well.

Recommendations for Action

Federal government:

- Congress should ensure that organizations that provide direct relief and services, including LGBT organizations, are eligible for funding under CARES Act and future emergency support measures.
- Consistent with the Supreme Court's recent decision in Bostock v. Clayton County, HHS should issue a regulation affirming that Section 1557 of the Affordable Care Act prohibits discrimination based on sexual orientation and gender identity.
- Consistent with the Supreme Court's recent decision in *Bostock v. Clayton* County, HUD should withdraw its proposed rule reversing the Obama Administration's Equal Access Rule, which required that Housing and Urban Department programs, including certain shelters, were open to all eligible families and individuals "without regard to actual or perceived sexual orientation, gender identity, or marital status."
- HHS, DOJ, and other relevant agencies should clarify that the Religious Freedom Restoration Act and other religion-related protections do not justify discrimination against LGBT individuals.
- FDA should remove all vestiges of its ban on blood donation by men who have sex with men from its blood donation guidance, so that the LGBT community is not excluded from assisting in the COVID-19 relief effort.
- Congress should pass additional legislation along the lines of the CARES Act that expands measures that assist lower income individuals, including food stamp, unemployment, and related benefits.
- CDC should collect (and ask state and local agencies to collect) data regarding individuals' sexual orientation and gender identity. This may, in part, be modeled on data collection in the National Health Interview Survey.

State governments:

- The appropriate state agencies and legislatures should fund community organizations including LGBT community centers, and ensure they are subject to protection against evictions and rent increases.
- State attorneys general should clarify that sex discrimination prohibitions in public accommodation discrimination, present in all 50 states, prohibit discrimination based on sexual orientation and gender identity, to ensure that LGBT individuals have access to essential services.
- The appropriate state agencies and legislatures should increase funding and support for homeless shelters, especially shelters dedicated to LGBT groups.
- The appropriate state entities should carry out Medicaid expansion.
- Governors and other authorized officers should clarify in emergency orders that LGBT focused services—including access to HIV medication and gender confirmation services—remain essential.
- State departments of education and school boards should require schools to provide support services via Zoom and other online outlets for LGBT students.
- State health departments should follow the lead of Pennsylvania and California in collecting data on sexual orientation and gender identity.

Local governments:

- Local agencies such as local school boards or public health departments should create safe virtual spaces and facilities for LGBT young people and seniors to engage with each other.
- Local health departments should develop programs that offer support to LGBT seniors.
- Local health departments should, where possible, rely on services and contracting with organizations that do not maintain moral or religious beliefs that promote sexual orientation or gender identity discrimination.
- Local health departments should provide resources such as COVID tests and the like to LGBT community centers.

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Reversing Immigration Law's Adverse Impact on Health

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SUMMARY. Immigration laws and policies have long served to magnify the social vulnerability of immigrants and members of their communities. These vulnerabilities have worked alongside the punitive, anti-immigration policies that the Trump administration pursued both before and during the pandemic to place immigrants and their communities at disproportionate risk for COVID-19. In addition, anti-immigrant policies during the pandemic helped to distort and undermine the nation's response to the pandemic. In order to prevent an equally dismal response to the next public health crisis, we need to more fully understand the mechanisms through which immigration laws intersect with the social determinants of health to enhance vulnerability to pandemics. We also cannot simply repeal the Trump administration's policies. Rather, we need to comprehensively reform immigration laws to end the punitive policies that heighten vulnerability to disease.

Introduction

COVID-19 struck the United States just as the Trump administration's restrictive and punitive approach to immigration reached its apex. Far from protecting the nation's health, these policies combined with pre-existing immigration laws and policies to heighten the pandemic's toll. They did so by 1) increasing social vulnerability in communities with large numbers of immigrants, 2) detaining immigrants in prisons and detention camps that served as "tinder boxes" for infection, and 3) distorting and undermining science-based public health policies.

As the Biden administration begins to develop and implement its own immigration policies, it is important to reassess how immigration laws and policies affect our capacity to prepare for and respond to public health crises. Building upon Chapter 33 in *Assessing Legal Responses to COVID-19: Volume I*, this Chapter begins that task (Parmet, 2020). The conclusion is plain: rolling back the most egregious Trump policies will not suffice. To avoid repeating our failed response to the pandemic, we must end the punitive approach to immigration.

This Chapter starts by providing a brief overview of what is known about the pandemic's impact on immigrants and their communities. It then reviews how U.S. law increased immigrants' social vulnerability before and during the Trump administration. The Chapter concludes by discussing the reforms that are needed moving forward to remedy immigration law's negative impact on our capacity to protect public health during a pandemic.

COVID-19's Impact on Immigrants and Their Communities

Documenting the pandemic's impact on immigrants is challenging. Neither the Centers for Disease Control and Prevention (CDC) nor states report cases or deaths by immigration status. Further, the more than 46 million immigrants living in the United States, 22 million of whom are noncitizens, form a highly heterogeneous population, differentiated by immigration, citizenship and socio-economic status, as well as race and ethnicity (Artiga & Rae, 2020). In addition, any discussion of the pandemic's toll on immigrants needs to note that many immigrants live in mixed-status families. More than two-thirds of noncitizens live in a household with a citizen, and around 13% of U.S. citizen children have a noncitizen parent (Artiga & Rae, 2020). Thus policies that increase immigrants' vulnerability to infectious diseases invariably affect native-born and naturalized citizens.

Although it is impossible to know the full extent of the pandemic's toll on immigrants, communities with high numbers of noncitizens were especially hard hit. In Massachusetts, "the proportion of foreign-born noncitizens was the strongest predictor of the burden of COVID-19 cases within a community" (Figueroa et al, 2020). Hispanic and Latino populations, in which approximately 50% of individuals are immigrants, have faced an especially high toll (Poulson et al, 2020).

Social determinants, including housing (living in larger households) and employment as "essential workers" have helped to enhance Hispanic vulnerability to COVID-19 (Figueroa et al., 2020). Noncitizens are also more likely than citizens (33% compared to 9%) to lack health insurance (Artiga & Rae, 2020). Structural racism constitutes another critical compounding factor. Poulson and colleagues, for example, found that Black Hispanics living in the United States have experienced worse outcomes from COVID-19 than other Hispanic people (Poulson et al, 2020). Despite these divergent and intersectional effects, immigration laws are implicated because of the multiple ways they heighten socio-

economic vulnerability. Reforming these laws is essential to improving our capacity to withstand the next pandemic.

Immigration Law's Impact on Social Vulnerability

The legal roots of the problem. Even before the Trump administration, scholars had identified immigration as a social determinant of health (Castañeda et al., 2015). Throughout American history, immigrants have been viewed as "less deserving" and have faced a wide range of social barriers to health care, housing, higher education, and employment security. Federal and state laws relating to the status of immigrants within the country reinforce these barriers.

In 1996, during a period of intense xenophobia, Congress extended barriers to noncitizen immigrants living in the United States through the enactment of the Personal Responsibility and Work Opportunity Reconciliation Act (PRWORA) and the Illegal Immigration Reform and Immigration Responsibility Act (IIRIRA).

IIRIRA aimed to enhance immigration enforcement. It increased resources for the Border Patrol, appropriated funds for construction of a fence on the southern border, and authorized expedited removal for certain undocumented immigrants. IIRIRA thus ushered in an era of heightened immigration enforcement and increased deportations that has increased fear and stress among noncitizens and members of their families. These stresses have been associated with a range of adverse health conditions (Castañeda et al., 2015).

PRWORA endorsed the widely-held misimpression that immigrants come to the United States in large numbers to access public benefits. Proclaiming that immigrants should be "self-sufficient," the Act barred undocumented immigrants from accessing most federally-funded benefits, including Medicaid. It also imposed a five-year ban during which most classes of lawfully present noncitizens remain ineligible for most federally-funded benefits (Parmet, 2020). The Act, however, exempted expenses related to testing, treating, and immunizations for communicable diseases, and allowed states to cover emergency medical treatment for ineligible noncitizens through what is known as the "emergency Medicaid" program.

Since PRWORA's enactment, Congress has softened its impact by granting states the option to enroll lawfully present children and pregnant people with or without documentation in Medicaid and the Children's Health Insurance Program. Many states, however, have not taken advantage of these provisions (Parmet, 2020). Further, although the Affordable Care Act permits lawfully present noncitizens to purchase insurance on the exchanges, it maintained PRWORA's restrictions on undocumented immigrants, as well as the five-year ban applicable to lawfully present immigrants. Hence even before President Trump took office, many noncitizens were excluded from large portions of the social safety net, leaving them and their families less likely to have health insurance or a regular source of health care (Parmet, 2020).

The Trump administration's restrictionist policies meet the pandemic. As discussed more fully in Chapter 33 of Volume I, several Trump administration regulatory actions increased noncitizens' vulnerability to COVID-19 and helped to spread the disease throughout the general population. In addition to pushing for a wall on the southern border, the Trump administration adopted a draconian approach to immigration enforcement, including through the use of family separation. It also to sought repeal the Deferred Action for Childhood Arrivals (DACA) program, end temporary protective status (TPS) for hundreds of thousands of immigrants, add a citizenship question to the census, and require asylum seekers crossing the southern border to "remain in Mexico" while their petitions were heard. Although some of these policies were overturned by the courts or reversed due to political blowback, they exacerbated fear and insecurity, leaving an already socially vulnerable population even more vulnerable.

The public charge rule played a particularly important role in augmenting immigrants' fear. The rule, which went into effect in February 2020, requires immigration officials to consider an immigrants receipt of non-cash benefits, including supplemental nutrition assistance (SNAP), housing subsidies, and federally-funded health insurance, as well health insurance status and income in determining whether the immigrant is likely to become at any point a public charge, and hence ineligible to enter the U.S. or receive permanent residency status(Parmet, 2020). Due to PRWORA, few immigrants who are subject to the rule are actually eligible for most of the listed benefits. Nevertheless, the rule created great fear among immigrants — even among those who are not subject to it — and has led many to refrain from interacting with the health care system or accessing vital benefits (Capps et al., 2020).

Access to benefits during the pandemic. In response to the pandemic, on March 13, 2020, United States Citizenship and Immigration Services (USCIS) announced that it would not consider public support for "testing, treatment, nor preventive care (including vaccines, if a vaccine becomes available) related to COVID-19 as part of the public charge inadmissibility determination" (Parmet, 2020). USCIS further stated that immigrants who lost their job due to the pandemic could submit evidence to that effect for their public charge determination. USCIS did not, however, suspend the rule during the pandemic. Nor did it embark on a campaign to inform noncitizens that COVID-related treatment would not be considered in the public charge determination. Instead, it continued to defend the rule against legal challenges, obtaining stays from injunctions imposed by lower courts even as the pandemic ravaged immigrant communities (Parmet, 2020).

Adding to these vulnerabilities was the fact that many noncitizens were denied access to some of the support that Congress provided in the pandemic relief legislation. For example, the $1,200 cash assistance provided under the Coronavirus Aid, Relief and Economic Security (CARES Act) was limited to citizens and immigrants with Social Security numbers. This barred citizens and legal permanent residents who are married to undocumented immigrants without a Social Security number from receiving relief. The Coronavirus Response and Relief Supplemental Appropriations Act, signed by President Trump in December 2020, remedied this by making citizens and legal permanent residents who file jointly

with an undocumented taxpayer retroactively eligible for $1,200 per household (plus $500 per child), as well as the additional $600 for adults, and $600 per child made available to all taxpayers under the Act (Montoya-Galvez, 2020).

Undocumented workers were also unable to access the unemployment compensation provided by the Families First Coronavirus Response Act. Hence, they often had little choice but to work in unsafe conditions, and to continue doing so even if they or someone in their household was ill (Arango et al, 2020). In addition, although the funding provided by the CARES Act for no-cost testing, treatment, and vaccinations for uninsured individuals did not require providers to confirm patients' immigration status, funding was limited for COVID-19 treatment and prevention, meaning that patients who seek care uncertain about their diagnosis faced the risk of receiving medical bills they cannot afford.

Nebraska Governor Pete Ricketts decided to be even more punitive, putting undocumented workers at the back of the line for vaccination (Armus, 2020). Although such punitive measures may appear to be limited to undocumented residents, their impact will be felt more widely. Noncitizens do not live or work apart from the rest of the population. Indeed, because so many noncitizens work in health care and other essential services, such policies threaten the health of the entire population.

The dangers of detention. Throughout the pandemic, noncitizens in detention faced enhanced risks. A September 2020 report of the House Committee on Homeland Security found that even before the pandemic, Immigration & Customs Enforcement (ICE) "ignor[ed] medical issues raised by detainees, offer[ed] poor mental health care services, and in one case, allow[ed] medical care to deteriorate to the point that it became necessary to transfer detainees to different facilities" (House Committee, 2020).

These problems continued throughout the pandemic. Although ICE reduced the population in some detention facilities, it has continued to conduct enforcement proceedings and tens of thousands of immigrants remained in custody throughout the pandemic. According to the American Bar Association, more than 7,600 individuals in ICE custody had tested positive as December 3, 2020 (American Bar Association, 2020). As of September 2020, six detainees had died in ICE custody due to COVID-19 (House Homeland Security, 2020). The full extent of the pandemic's toll on detainees, however, remains unknown.

Dozens of lawsuits have challenged the conditions of confinement during the pandemic (Parmet 2020). In one notable case, *Angel de Jesus Zepeda Rivas v. Jennings*, a federal judge from the Northern District of California found on December 3, 2020, that a privately-run detention facility and ICE had failed to implement a plan to minimize the risk, had deliberately failed to test detainees and staff, and had avoided undertaking safety measures. Nevertheless, many courts denied petitions by individual detainees who could not show a special risk factor for severe disease due to COVID-19 (Parmet, 2020).

Distorting public health. Throughout history, societies have blamed and scapegoated non-nationals and racial minorities for epidemics. The COVID-19 pandemic was no exception. President Trump and his supporters frequently called SARS-COV-2 "the China virus." This xenophobic lens helped frame and distort the federal government's response to the virus. For example, the travel bans that were imposed in the winter and spring of 2020 were issued under the President's immigration authority, rather than the Public Health Services Act, and were predicated on citizenship and immigration status, rather than exposure to the virus. At least early in the pandemic, President Trump seemed to take the position that the United States would be safe from the coronavirus as long as non-nationals were kept out of the country (Parmet, 2020). In the early days of his administration, President Biden has also relied on his immigration authorities to bar entry by non-nationals traveling from South Africa and Brazil, in an effort to keep out new variants of SARS-COV-2.

The CDC's promulgation of an emergency regulation permitting it to bar non-nationals from nations from which there is a "serious danger" of introduction of a communicable disease provides a different example of how the Trump administration's anti-immigration policies distorted the pandemic response (Parmet, 2020). Pursuant to this regulation, CDC issued an order closing the border with Mexico, which the Department of Homeland Security promptly used to override asylum law and expel asylum seekers (Parmet, 2020). Despite its different approach on immigration, as of February 2021, the Biden administration has maintained this order, continuing the tradition of hijacking public health policy in the service of immigration restriction (Miroff et al., 2021).

Moving Forward

America's experience with COVID-19 demonstrates that comprehensive immigration reform, such as President Biden has called for, is essential to an effective pandemic response. As long as millions of immigrants who live and work in the United States experience fear and insecurity, without access to basic benefits, large swaths of the population will remain at heightened risk of novel infectious diseases that can rapidly spread to the broader population. For that reason, comprehensive immigration reform is an essential element of pandemic preparedness.

While a full discussion of the contours of any immigration reform measure is beyond the scope of this Chapter, any reform must offer a rapid path to legalization for immigrants who reside in the United States. It should also reduce our reliance on enforcement, especially among immigrant communities living within the country, and detention of immigrants who pose no risk to public safety. Most importantly, any immigration reform must end the harmful practice of attempting to deter immigration by increasing vulnerability among immigrants. For this reason, any immigration reform bill should repeal the public charge provision in the INA, as well as the punitive restrictions in PRWORA that have blocked and deterred immigrants from accessing critical public benefits. These exclusions have led to lower rates of health insurance among noncitizens and have left the nation as a whole less able to respond effectively to public health emergencies.

Although only Congress can enact the type of comprehensive reform necessary to ensure that immigration laws no longer weaken our ability to respond to a pandemic, congressional action on immigration has long proven elusive. With the Democrats having only slim majorities in Congress, and our highly polarized politics, the prospects for imminent action remain uncertain. It will, therefore, be essential for the Biden administration, and the states, to do what they can do.

Much can be done at the federal administrative level. Already, President Biden has called upon his Department of Homeland Security (DHS) to reverse the Trump administration's efforts to end DACA, and to restore TPS for some immigrants. In addition, on February 1, 2021, DHS issued a statement encouraging everyone to be vaccinated regardless of immigration status, and promising that ICE will not conduct enforcement actions near vaccine distribution sites or health care facilities. And on February 2, 2021, the president directed DHS to review the public charge rule. Presumably, the review will lead DHS to begin the process of repealing the rule. In the meantime, DHS should repeal it for the duration of the pandemic.

The Biden administration can also immediately begin to reduce the number of immigrants in detention centers, jails, and prisons. It can also stop enforcement raids when public safety is not at stake, and begin rulemaking to prohibit ICE from receiving information from health care providers and public health agencies.

The Biden administration can also take several steps to increase health insurance coverage among non-citizens. In addition to suspending and eventually rolling back the public charge rule, it can reverse an Obama-era guidance holding that DACA recipients were ineligible to purchase insurance on the Affordable Care Act exchanges.

Finally, the Biden administration can and must stop the dangerous conflation of public health and immigration policies. CDC guidance and orders must be based solely on public health grounds, not aimed at furthering immigration goals.

Although states have less authority than the federal government over immigration, they can and should expand coverage to all categories of noncitizens who are eligible for federally-funded health insurance. States should also offer state-funded health insurance and other benefits to noncitizens who are ineligible for federal support. As the pandemic has shown, once a public health emergency strikes, states are forced to respond to communities facing higher rates of disease. Far better to provide coverage and care to these communities before they become "hot spots."

States can also ensure that COVID-19 vaccines are widely available to immigrants, regardless of legal or insurance status. Most importantly, states must make sure that information about the availability of vaccines is made available in all languages that are spoken in their communities.

Likewise, both the Biden administration and states need to undertake a robust messaging campaign to counter the false belief that immigrants endanger the health of Americans. Federal and state leaders also need to make clear that immigrants will not face adverse immigration consequences for being sick, seeking care, speaking with health officials, getting vaccinated or reporting unsafe work conditions. These messages need to be in all languages spoken in a community, and government officials at all levels need to work with grass root community leaders to help reduce the fear and restore the trust among newcomers to America.

Restoring that trust, and lessening the fear will not be easy. Unless we do it, we will never be prepared.

Recommendations for Action

Federal government:

- Congress should enact comprehensive immigration reform that provides undocumented immigrants with a pathway to citizenship and reduces immigration insecurity.
- Congress should repeal the provisions within PRWORA that bar undocumented immigrants and those with less than five years of legal status from obtaining federally-funded benefits for which they would otherwise be eligible.
- Congress should repeal the public charge provision in the Immigration and Naturalization Act.
- Unless Congress repeals the public charge provision in the Immigration and Naturalization Act, the Department of Homeland Security should suspend the public charge rule during the pandemic and take steps to begin to repeal and replace it with one that codifies past practice.
- ICE should suspend immigration raids during the pandemic except when necessary for public safety, and should depopulate detention facilities to the extent compatible with public safety.

State governments:

- States should provide Medicaid and CHIP to all otherwise eligible noncitizens, and use their own funds to provide coverage to immigrants who are ineligible for federally-funded coverage.
- States must ensure that COVID-19 vaccines are accessible and available to noncitizens, regardless of immigration and insurance status.

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Protecting the Rights and Wellbeing of People with Disabilities during the COVID-19 Pandemic

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SUMMARY. The COVID-19 pandemic has exposed and exacerbated significant inequities experienced by people with disabilities. It has also emphasized the value of legal protections against discrimination based on disability. The Americans with Disabilities Act was enacted 30 years ago to eliminate discrimination against people with disabilities and ensure equal opportunity across major areas of American life (ADA, 2008). Together with an earlier law, the Rehabilitation Act of 1973 (Rehabilitation Act, 2012), this landmark civil rights law impacts a broad range of issues raised by the COVID-19 pandemic and protects a large and growing number of Americans. This Chapter focuses on application of these laws to health care and employment during the pandemic. These laws are powerful tools to protect the rights and well-being of people with disabilities, but they require robust enforcement. Enforcing agencies have provided COVID-19-specific guidance on the application of the laws to health care and employment. Further action is needed, as unresolved legal questions, gaps in protections, lack of knowledge of and noncompliance with disability rights laws, and a lack of data limit the impact of these laws. Recommendations for policymakers to ensure COVID-19 responses respects the rights and wellbeing of people with disabilities include: robust enforcement of the laws; clear and current agency guidance on how to comply with the laws; education about the requirements of the laws, especially in health care settings; and improved data collection and reporting.

Introduction

One in four Americans — a diverse group of 61 million people — experience some form of disability (Okoro et al., 2018). Disability is diverse, and certain racial and ethnic populations have much higher rates of disability than others. As a group, people with disabilities experience significant disparities in education, employment, poverty, access to health care, food security, housing, transportation, and exposure to crime and domestic violence (Pendo & Iezzoni, 2020). Intersections with race, ethnicity, gender, LGBTQ status, and other characteristics may intensify certain inequities. For example, members of underserved racial and ethnic groups with disabilities experience greater disparities in health status and access to health care (Yee et al., 2019).

The pandemic has increased unemployment and economic insecurity for people with disabilities and tested the scope of the ADA's protections in the workplace. It has also worsened health disparities experienced by people with disabilities and highlighted well-founded concerns of discrimination and unequal treatment if they do seek health care services (Pendo & Iezzoni, 2020). The initial wave of the pandemic brought attention to two actions taken by employers to reduce the threat of COVID-19 infection in the workplace: COVID-19 screening and testing programs, and expanded remote work policies. In health care settings, COVID-19 highlighted policies regarding allocation of scarce medical resources and crisis standards of care. For more information on the application of the ADA to these early developments, please see Chapter 34 in *Assessing Legal Responses to COVID-19: Volume I*. This Chapter will focus on emerging issues as employees' return to the workplace, and legal strategies to address disability health disparities and the lack of disability data.

The Americans with Disabilities Act

The ADA was enacted 30 years ago to eliminate disability discrimination and ensure equal opportunity across major areas of American life. It expands the protections of an earlier law, the Rehabilitation Act, that prohibits disability discrimination in programs and activities that receive federal financial assistance

and in federal employment (Rehabilitation Act, 2012). The requirements of the ADA are illustrated in Table 34.1.

Although this Chapter focuses on the ADA, there are federal laws that prohibit discrimination based on disability in telecommunications, housing, air travel, voting, and education (Department of Justice Civil Rights Division, 2009). States and local governments may also have laws that prohibit disability discrimination.

The ADA impacts a broad range of issues raised by the COVID-19 pandemic. Title I applies to disability accommodations such as remote work, as well as COVID-19 screening, testing and vaccination policies. Together, ADA Titles II and III and the Rehabilitation Act apply to policies and practices of public hospitals and clinical practices, including allocation of scarce medical resources and crisis standards of care. These laws also apply to state, local, and private public health measures, such as physical distancing and mask-wearing requirements (Pendo et al., 2020).

The ADA protects a large and growing number of Americans. The ADA protects any individual who has a physical or mental impairment that substantially limits one or more major life activities, a record of impairment, or is regarded as impaired (ADA, 2008). This definition is meant to be construed in favor of broad coverage of individuals. For example, "major life activities" includes a long, non-exclusive list of both activities and bodily functions.

At the beginning of the pandemic, the focus was on disability protections for the millions of Americans with underlying health conditions that put them at greater risk of severe illness from COVID-19. ADA regulations provide that conditions such as cancer, lung disease, serious heart conditions, immune-suppressing conditions, and diabetes are considered disabilities in virtually all cases. COVID-19 has the potential to increase the number of people who meet this definition. For example, high blood pressure also puts individuals at greater risk of severe illness from COVID-19. This very common condition can be a disability, even when mitigated by medication. The impact of COVID-19 on mental health is also significant (see Chapter 19). New and preexisting mental health conditions can be ADA disabilities.

Although some uncertainty exists, COVID-19 infection itself may meet the definition of disability. Infection affects the immune system and normal cell growth even absent clinical symptoms and can substantially limit the major life activity or operation of one or more bodily systems or organs. COVID-19 infection can also be transmitted to others even absent clinical symptoms, which limits the ability to safely interact with others. Long-term mental and physical effects of COVID-19 infection and disease may also qualify as disabilities.

Table 36.1. Summary of ADA Requirements by Title

TITLE	COVERED ENTITIES AND REQUIREMENTS
Title I (Employment)	Requires equal access to employment opportunities, and that employers provide reasonable accommodations for applicants and employees with disabilities. Limits employer collection of medical and disability-related information from all applicants and employees.
Title II (Public Entities)	Prohibits discrimination against people with disability in any services, programs, and activities offered by states and local governments, and requires reasonable modifications when necessary.
Title III (Public Accommodation)	Prohibits discrimination by private places of public accommodation, such as restaurants, retail establishments, private clinical practices, and other businesses open to the public against people with disabilities.
Title IV (Telecommunications)	Requires telephone and internet companies provide accessible means of communication for people with disability as well as closed captioning of federally funded public service announcements
Title V (Miscellaneous Provisions)	Includes miscellaneous provisions that apply to the ADA as a whole including the responsibility of certain federal agencies for disseminating information and providing technical assistance for those seeking protection under the law.

Workplace Protections

COVID-19 Vaccination Policies

Title I of the ADA permits accurate and reliable methods of COVID-19 screening and testing of employees because the virus poses a direct threat to health and safety. It also limits the collection of medical and disability-related information in the workplace (see Chapter 34 in *Assessing Legal Responses to COVID-19: Volume I*).

The availability of COVID-19 vaccinations raises new questions about the ADA's protections. Employers generally have the authority to impose vaccination requirements (Yang et al., 2020). Health care institutions, for example, often require employees receive vaccinations for contagious diseases such as influenza, measles, and rubella (Yang et al., 2020.). According to new guidance from the Equal Employment Opportunity Commission (EEOC), the ADA permits employers to encourage COVID-19 vaccination through voluntary programs. The ADA also permits employers to require COVID-19 vaccinations so long as they

consider reasonable accommodations for disability and religious reasons under the ADA and related laws (EEOC, 2020). But there are other unresolved legal questions about COVID-19 vaccine mandates because the vaccine was granted Emergency Use Authorization (EUA) (see Chapter 23), which requires recipients receive information about the option to accept or refuse the vaccine (EEOC, 2020).

COVID-19 and Remote Work as Accommodation

The ADA requires employers to make reasonable accommodations for employees with disabilities, which are affirmative steps that enable employees with disabilities to do their jobs. Accommodation decisions are made on a case-by-case basis and should be the product of an interactive process between the employer and employee. Employers are not required to provide the specific accommodation requested by the employee, so long as the alternative it offers adequately addresses the employee's needs and reasonably accommodates the disability.

Employers do not have to provide accommodations that pose an undue hardship (involving significant difficulty or expense) or a direct threat (a significant risk of substantial harm to the health or safety of the employee or others, which cannot be eliminated or reduced by a reasonable accommodation). For example, an employer can require an employee to stay home if the employee tests positive for COVID-19 or has COVID-19 symptoms. However, the employer should consider whether the direct threat can be minimized through a reasonable accommodation that allows the employee to stay on the job, such as working remotely. Employers must also consider reasonable accommodations for individuals who are at increased risk of COVID-19 due to underlying health conditions that meet the ADA definition of disability.

One-third to one-half of U.S. workers report working from home during the pandemic (Dingel & Neiman, 2020). We may see more conflicts as employers seek to bring employees back to the workplace. For example, an office worker may request to work from home to accommodate a medical condition that puts them at greater risk of serious COVID-19 disease. The employer might refuse that request because it has instituted protective measures such as temperature screenings, mask requirements, enhanced cleaning, and physical distancing requirements. If so, the employer must show its protective measures adequately address the threat of infection to the employee and others in the workplace based on an individualized assessment of the risk using the best available objective medical evidence (EEOC, 2020). The employer would also need to address any arguments by the worker that the measures are inadequate, such as lack of enforcement of the mask requirement, or impracticality of physical distancing given the office layout.

Employers do not have to provide accommodations that eliminate an essential part of the job. If a job has been done successfully from home during the pandemic, it may be more difficult for the employer to argue that physical presence in the workplace is essential.

Expanded remote work policies may greatly benefit workers with disabilities, among others. But expanded remote work may heighten workplace inequities. First, not everyone is entitled to remote work as an accommodation. Employers are not required to provide ADA accommodations to employees who are at increased risk of COVID-19 due to a reason other than disability (such as age or ordinary pregnancy) or to employees with family members who are at risk. (EEOC, 2020). Second, not all jobs can be done remotely. Educators, managers, and professionals in technology, business, and law are most likely to be able to work remotely, while many employees in food service, construction, maintenance and repair, and production are unable to perform their jobs off-site (Dingel & Neiman, 2020).

Health and Health Care Issues

The ADA prohibits exclusion of or discrimination against people with disabilities in health care in state policies and health care services offered by public hospitals (Title II), and in private physician's offices and private hospitals (Title III). Section 1557 of the Patient Protection and Affordable Care Act (ACA) amends the Rehabilitation Act to provide additional protections against discrimination in health care. These laws require equal access to health care services for individuals with disability, subject to some limitations. Equal access includes: no exclusion of patients with disabilities; physical access to health care services and facilities, including accessible spaces and the removal of barriers; effective communication, including auxiliary aids and services such as the provision of sign language interpreters or materials in alternative formats; and a general duty to make reasonable modifications of health care policies, practices, and procedures when necessary to accommodate individual needs.

The initial wave of the pandemic brought attention to policies regarding allocation of scarce medical resources and crisis standards of care developed by states and health care facilities (Chapter 24). The U.S. Dept. of Health and Human Services (HHS) Office for Civil Rights (OCR) has made clear that policies may not explicitly or implicitly discriminate on the basis of disability (see Chapter 34 in *Assessing Legal Responses to COVID-19: Volume I*). An equitable approach requires considering past and present health inequities experienced by people with disabilities and others that may be intensified by these policies. These policies should also be publicly adopted and created with meaningful input from people with disabilities and others likely to be disadvantaged by these policies.

Disparities and Discrimination before COVID-19

People with disabilities experience significant disparities in health status, access to health care, and other social determinants of health (Pendo & Iezzoni, 2020). Intersections with other disadvantaged groups may compound these disparities. As mentioned in the introduction, members of underserved racial and ethnic groups with disabilities experience greater disparities in health status and access to health care (Yee, et al., 2019). Emerging evidence suggests LGBTQ individuals with disabilities are especially vulnerable to many of these disadvantages (Pendo & Iezzoni, 2020).

People with disabilities are at higher risk for COVID-19 infection and serious disease because of pre-existing disparities. A recent series of reports published by the National Council on Disability underscore how persistent devaluation of the lives of people with disabilities by the medical community, legislators, researchers, and others, perpetuates inequities in health and access to health care, including life-saving care (National Council on Disability, 2019). People with disabilities also have well-founded concerns about disability bias and discrimination if they do seek care, as these problems persist 30 years after the enactment of the ADA (Pendo & Iezzoni, 2020). It is clear that robust enforcement of nondiscrimination laws must be coupled with education and training.

Lack of Disability Data

We lack data related to COVID-19 testing, infections, and outcomes for people with disabilities. As with other disproportionately impacted groups, data is needed to assess risks for people with disabilities, to develop health protection measures, and to identify and address important disparities. Disaggregated data related to disability would also provide information about the intersection of disability with race, ethnicity, gender, sexual orientation, and other groups for which data is collected (Yee et al., 2019). There has been long overdue attention to individuals in nursing homes and long-term care facilities during the pandemic (see Chapter 20). We also need data related to home and community-based services and providers which are critical to people with disabilities who live in the community. There are data collection standards for disability status that could be used for federal, state, and local collection and reporting of COVID-19 data. Section 4302 of the ACA already requires all federally conducted or supported health care and public health programs to collect data on disability status using, at a minimum, the six disability questions in the American Community Survey used to gauge disability among the U.S. population (Pendo & Iezzoni, 2020).

More broadly, collecting better disability data at the federal, state, and local levels is needed to identify and address critical issues of health disparities and health equity experienced by people with disabilities. For example, the ACA directs HHS to identify locations where individuals with disabilities access different types of care and to determine the number of providers with accessible facilities and accessible medical and diagnostic equipment and the number of employees trained in disability awareness and in caring for patients with disabilities. However, this data has not been collected (Pendo & Iezzoni, 2020).

Recommendations for Action

Federal government:

- To assure COVID-19 response respects the rights and well-being of people with disabilities, federal agencies should provide clear, ongoing legal guidance. Specifically:
  - The OCR should continue to enforce and provide COVID-specific guidance on the requirements of the ADA, Rehabilitation Act, and Section 1557 of the ACA for health care providers, institutions, and systems regarding medical allocation policies, hospital visitor policies, and other policies that impact care for people with disabilities.
  - Following the example of the EEOC's guidance for private employers, the DOJ should provide similar guidance on the requirements of the ADA and Rehabilitation Act in COVID-related policies adopted by state, local, and retail and other business entities, including mask-wearing policies.
  - The EEOC should provide clear guidance on when COVID-19 infection, disease, and lasting physical and mental effects are ADA disabilities.
- Congress should fund and require HHS to collect and publicly report standardized data using, at a minimum, the data collection standards for disability that have been developed under the ACA in three areas:
  - COVID-19 testing, infections, treatment, and outcomes;
  - Home and community-based services necessary to people with disabilities who live in the community during COVID-19;
  - As required by the ACA, identification of locations where individuals with disabilities access care, their accessibility, and the number of employees trained in disability awareness and in caring for patients with disabilities in those locations.

State governments:

- Governors should instruct public health officials to incorporate equity considerations and address the needs of people with disabilities in all COVID-19 orders, policies and programs, including provision of high-quality personal protective equipment (PPE) to providers of home and community-based services and other caregivers for people with disabilities living in the community.
- To assure COVID-19 response respects the rights and wellbeing of people with disabilities, state agencies should:
  - Actively enforce and provide COVID-specific guidance on the requirements of state laws that prohibit discrimination based on disability.
  - Provide clear guidance on when COVID-19 infection, disease, and lasting physical and mental effects are protected as disabilities under state anti-discrimination laws (see, e.g., NYC Human Rights, 2021).
  - Review and revise state and local policies related to COVID-19, including medical allocation policies, hospital visitor policies, and mask-wearing policies, to ensure they comply with requirements of federal and state disability rights law.
- Pursuant to federal direction or on their own initiative, states should collect and publicly report standardized data using, at a minimum, the data collection standards for disability that have been developed under the ACA in the three areas identified for federal data collection above.
- States should adopt policies that encourage employers to:
  - Allow all employees to work remotely where possible, regardless of disability.
  - Encourage employer adoption of voluntary COVID-19 vaccination policies when possible and ensure mandatory COVID-19 policies comply with requirements of federal and state disability rights law.

Local governments:

- To assure COVID-19 response respects the rights and wellbeing of people with disabilities, local agencies should take the same steps to enforce, review and revise local laws and policies as recommended for State agencies in connection with state laws above.
- Pursuant to federal or state direction or on their own initiative, local governments should require the collection and public reporting of standardized data using, at a minimum, the data collection standards for disability that have been developed under the ACA in the three areas identified for federal data collection above.
- As recommended for state governments above, local governments should adopt policies that encourage employers to broadly allow remote work and to adopt vaccination policies that comply with federal and state disability rights law.

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Fostering the Civil Rights of Health

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SUMMARY. In 2020, structural racism in the United States forcefully entered the public consciousness. The disparate impacts of COVID-19 on people of color, coupled with massive protests and organizing against racialized state violence (which themselves were met with racialized state violence), inspired many American policymakers, institutions, and organizations to craft race-aware responses to the pandemic. Race-aware remedies to the harms of COVID-19 are essential and long overdue. Nonetheless, in the context of long-standing and pervasive structural racism, race-aware policies continue to be blocked or challenged. This Chapter uses the "civil rights of health" framework introduced in Volume I to suggest how short-term policymaking on behalf of racialized vulnerable populations must be embedded in longer-term strategies for building an inclusive sense of the common good, starting with an "infrastructure of facts."

Introduction

The civil rights of health framework urges public health, civil rights, and social justice movements to achieve together what they cannot alone. It is premised on the recognition that ending structural racism is necessary to ending racial health disparities.

Under the framework, government entities and advocates tasked with the protection of civil rights should draw on the social determinants of health literature to pinpoint how racial discrimination and marginalization across systems create and sustain differential vulnerability to COVID-19. Public health advocates must address discrimination as a health issue and fully embrace anti-discrimination law and policy as an essential public good necessary for health equity. Finally, civil rights and public health professionals should embrace the expertise and equal partnership of the frontline communities leading today's social justice movements in eliminating structural racism.

An endemic challenge in this work is the tension between universal policies and policies targeted to benefit marginalized populations. Precisely because structural racism is so embedded in American society, attempts to uproot it are often met with fierce opposition. In Volume I, we recommended a "targeted universalism" approach that combines attention to stigmatized populations with universal policies. For more information on the civil rights of health framework and the first round of recommendations, please see Chapter 35 in *Assessing Legal Responses to COVID-19: Volume I*.

The Introduction and Assessment in Volume I also discussed a series of disconnects in governance and advocacy that contribute to the disproportionate toll of COVID-19 on people of color. This Chapter builds on our account of those disconnects by focusing on narrative disconnects that have fractured policymakers and the public, leading to disagreements about basic health-related facts, as well as deficits in the collective capacity necessary to address a crisis on the scale of COVID-19.

Racialized health disparities in the United States are ultimately rooted in subordination (Harris & Pamucku, 2020). Subordination refers not only to interpersonal racism but, importantly, institutional and structural dynamics that tilt the playing field against Indigenous peoples and communities of color. The pandemic provides a vivid demonstration of these dynamics. It is now well documented that COVID-19 has taken a disproportionate toll on the health, wealth, and longevity of people of color. In response, as this Chapter noted and recommended in Volume I, many state and local governments have explicitly connected the dots between racism and health, with some declaring racism itself to be a public health crisis. Now, governments and non-governmental advocates must decide how to craft policy in response to this recognition. This Chapter recommends that these efforts begin by addressing the information disconnect that stymies the adoption and implementation of race-aware policies.

The Racism at the Root of the "Infodemic" Threatening the Nation

By early 2020, the World Health Organization warned that COVID-19 had created not only a pandemic, but also an "infodemic" (Zarocostas, 2020). Lack of agreement on basic facts about the coronavirus has contributed to a weakening of the nation's ability to adopt evidence-based infection mitigation strategies such as mask wearing and social/physical distancing, and has even fueled unfounded claims that the pandemic itself is a hoax, and that the virus is no more dangerous than the common cold. Worse, the atmosphere of confusion and uncertainty engendered by the lack of a shared infrastructure of facts has enabled conspiracy theories

and fact-free, overtly racist and xenophobic narratives to rush in to fill the void — some promoted by the previous president himself, such as the idea that SARS-CoV-2 was created in a Chinese laboratory and deliberately released.

The context of this infodemic was a four-year war on facts in the physical sciences, the social sciences, medicine, and history. The culmination of the previous administration's attack on truth was the violent effort to overturn the results of the 2020 presidential election. Motivated by Trump's baseless claims that the election was "stolen," an armed mob of supporters stormed the Capitol building during the certification of election results. The mob, largely made up of white people, carried racially charged and anti-Semitic symbols through the Capitol, including nooses, Confederate flags, and Nazi references.

Though shocking, the previous administration's assault on truth — and the literal assault on the Capitol — only dramatized a preexisting condition: a chronic infodemic regarding our nation's racial past and present. The United States is distinctive among other wealthy nations for its fragile social safety net, and social scientists have traced this unwillingness to provide generous access to public goods to our national history of racism (Alesina et al., 2001). Yet, today many Americans hold misleading, partial, or downright incorrect understandings of this history and of present-day structural racism (Lowen, 2018; Kendi, 2019; Zinn, 1990). This absence of a shared infrastructure of facts — including a recognition of structural racism — threatens our health, our social fabric, and the very mechanisms of our democracy.

Racism has, time and time again, blocked universal access to the material resources that we need for individual and collective flourishing (Pamukcu & Harris, 2020). Americans have been reluctant to support universal public benefit programs; instead, access to public benefits and programs has often been based on race. This has occurred at all levels of society, from the actions of government (such as the exclusion of agricultural and domestic workers from New Deal programs) to private actors (such as lending discrimination on the basis of racial geography by banks and Realtors, known as "redlining"). For example, in the wake of *Brown v. Board of Education*, as Carol Anderson has recently recounted, the desire to prevent Black people from having access to public goods led state and local governments to close swimming pools, schools, and eliminate other public services altogether, rather than see them be open to all (Anderson, 2016). Even in the present day, as Jonathan Metzl has documented, many Americans would prefer to go without access to public benefits such as health insurance than to see them go to "undeserving" people of color (Metzel, 2019). Even where benefits programs exist, the narrative of "deserving" versus "undeserving" communities has induced governments to care more about preventing fraud than about providing badly-needed support to vulnerable populations.

One reason why the United States has been a worldwide leader in pandemic illness and death is the absence of a sense of common good, a basic building block of democratic governance. The sense that "we're all in this together" is associated not only with individual willingness to wear a mask and socially distance, but also with public support for a strong social safety net. In the United States, however, racism has long stood in the way of recognizing the common good.

Fostering a Sense of the Common Good

The civil rights of health framework suggests that rebuilding an infrastructure of facts, including the facts of structural racism, can not only begin to ameliorate health disparities, but also to build a nationwide commitment to the common good — a commitment necessary to effectively combat COVID-19, strengthen public health infrastructure, and achieve health equity. This framework suggests at least two key priorities for combatting the infodemic that has worsened the harms of COVID-19 and sustained health disparities for generations:

1. Foster a sense of the common good by connecting the dots between improving national health outcomes and addressing structural racism, and
2. Use the principles of targeted universalism to build a shared "infrastructure of facts."

This Chapter proposes that governments, including but not limited to the current presidential administration, undertake efforts to establish an infrastructure of facts to build the ties and trust necessary to prevent and address ongoing and future racialized threats to our collective health and safety.

In the first Volume, our recommendations focused on the need for "targeted universalism" as a framework for developing policy. This Chapter recommends using the principles of targeted universalism to build an infrastructure of facts. This can be accomplished by developing a shared understanding of history that, without blaming and shaming individuals, includes the experiences of people of color and is honest about the role of the white supremacy in shaping modern-day institutions and systems.

Efforts to establish an inclusive infrastructure of facts would not start from scratch. Social justice movements, including the Movement for Black Lives, have already begun to lead the way. The recent widespread sharing on social media of videos of police and private violence against Black people has challenged the belief of many Americans, especially white Americans, that the United States is a colorblind society. The hashtag #SayHerName called public attention to violence against Black cis and trans women. And the creation of memes involving "Karens" and "Beckys" has raised awareness of the complicated role that white women play in releasing state violence. Access to shocking and heartbreaking video footage of police killings brought many non-Black people into the streets to protest police violence in the summer of 2020, and catapulted scholarly accounts of institutional and structural racism onto bestseller lists.

Well before 2020, in colleges and universities, faculty, administrators, and students had started working together to understand and address the ways in which slavery and land dispossession has been embedded in these institutions (Brown University, n.d.). In communities across the country, passionate

debates have taken place over public statuary and other memorials that honor white supremacists. Historians and archaeologists have discovered Black cemeteries and shed new light on white "race riots," ending decades of silence and evasion. Media, artists, and culture workers have brought the story of racism, especially slavery and its afterlife, into the public eye. Although some of this cultural work takes a heightened toll on Black mental health, it speaks to the urgent need for a collective shared reality and for increased awareness of the experiences of marginalized people that might otherwise be discredited or disbelieved.

Such projects generally do not, and are not intended to, build a feel-good "consensus;" indeed, they are likely to be controversial and their claims hotly contested. The aim, however, is not to eliminate debate, but to engage ordinary people, as well as "experts," in discussions about race that are based on a shared basic understanding of basic facts, including the racial health gap and the environmental and systemic forces that shape it.

Toward Health Justice: Supporting Truth and Reconciliation

Under a civil rights of health approach, government entities partner with their communities to build an infrastructure of facts by helping their communities come to a shared understanding of our racialized past and present. Such efforts would build the groundwork for more effective and equitable responses to public health crises in the future.

This Chapter recognizes particular promise in the mechanism of truth and reconciliation commissions (TRCs), which provide a more formal opportunity for this work of healing and shining a light on our shared past. Although the South African Truth and Reconciliation Commission is the most famous example, TRCs have also been convened in the United States at both the local and state level. A local example is the Greensboro, North Carolina Truth and Reconciliation Commission that ran from 2004 to 2006 to investigate a 1979 incident in which members of the Ku Klux Klan attacked and killed unarmed people at a civil rights march, with the apparent complicity of local law enforcement. A state example is the Maine Wabanaki-State Child Welfare Truth and Reconciliation Commission, which led a truth-seeking process from 2013 to 2015 to investigate the practice of taking Indigenous children in that state from their homes and placing them with white families (Truth & Reconciliation Commission, 2015).

Some U.S. observers and policymakers have called for a national TRC on racial justice. In June 2020, for example, California Congresswoman Barbara Lee announced legislation calling for the establishment of the first United States Commission on Truth, Racial Healing, and Transformation (Concurrent Resolution, 2020). However, a federal TRC would face intensely partisan divisions and the difficulty of building community at a national scale. TRCs might therefore be more practical and effective at the state and local level, where they can be scaled to communities and help build ties rooted in a shared sense of past and place. Recognizing this potential, district attorneys in Boston, Philadelphia, and San Francisco have recently announced they would each create commissions to address racism and police brutality.

The alliance of civil rights, public health, and social justice movements can catalyze and contextualize TRCs and other efforts to build the infrastructure of facts required to address structural racism as a driver of health disparities. Such efforts will strengthen our collective will and readiness to respond to the ongoing threat of COVID-19 which, like other widespread disasters, thrives in places where the fabric of our society is frayed. They are not meant to displace immediate policy responses to health disparities, but rather to complement them and prepare for a future in which a robust sense of the common good is truly inclusive and based in a shared infrastructure of facts.

Recommendations for Action

Federal government:

- Agencies should develop guidance for the use of "targeted universalism" as a policy and planning frame in order to benefit all populations while specifically addressing the harms of racism.
- The Biden administration should provide policy guidance to state and local governments on the establishment of truth and reconciliation committees.
- The Biden administration should issue an executive order establishing an interagency working group or a national task force to focus on addressing racial and health inequities exacerbated by COVID-19.
- Congress should support state and local truth and reconciliation committees by making financial resources available for such efforts.

State governments:

- State governments should work with agencies and departments to develop guidance on the use of "targeted universalism" as a policy and planning frame, in order to benefit all populations while specifically addressing the harms of racism.
- State governments should support state and local truth and reconciliation committees, including efforts located within specific agencies.

Local governments:

- Local governments should create and support truth and reconciliation committees, including efforts located within specific agencies such as school districts, prosecutors offices, and police departments.
- Local governments should recognize and address racism as an institutional and systemic issue, such as the proliferation of local government declarations characterizing racism as a public health crisis.
- Local governments should use "targeted universalism" as a policy and planning frame in order to benefit all populations while specifically addressing the harms of racism.
- Local governments should foster three-way partnership among civil rights, public health, and anti-discrimination movement leaders.

Tribal governments:

- Tribes should create and support truth and reconciliation committees.

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Closing Reflection: The Way Forward

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An Entanglement of Policies

One of the most difficult challenges facing the Biden administration will be undoing a profoundly unwise entanglement of policy decisions. To understand the true dimension of that problem, it helps to look at the document that most succinctly captures the thinking behind the Trump administration's policy regarding the pandemic: The Great Barrington Declaration. Although it was not published until October 2020, it summarized the thinking of the administration's most hyper-libertarian advisors, including Dr. Scott Atlas, and the Secretary of Health and Human Services, Alex Azar. The authors, a loose collective of epidemiologists and doctors, proposed a strategy they called Focused Protection. They asserted that "current lockdown policies" are causing "irreparable damage, with the underprivileged disproportionately harmed" (Great Barrington Declaration, 2020). It is worth noticing that in this version of reality, the more active agent of harm is not the actual virus, but "lockdowns." The expressed goal of the authors was "reaching herd immunity" by opening up *everything* — period — and soldiering through. According to them, encouraging community spread would "allow those who are at minimal risk of death to live their lives normally to build up immunity to the virus through natural infection, while better protecting those who are at highest risk." Sunetra Gupta, one of the three principle authors, told *The Daily Telegraph*: "[W]e're saying, let's just do this for the three months it takes for the pathogen to sweep through the population." Martin Kulldorff, another principle author, told Canada's *National Post* what he envisioned: "[A]nybody above 60, whether teacher or bus driver or janitor I think should not be working—if those in their 60s can't work from home they should be able to take a sabbatical (supported by social security) for three, four or whatever months it takes before there is immunity in the community that will protect everybody" (Kirkey, 2020).

There are innumerable ethical questions raised by such a proposition, not least its unproved assumption that the human population is anywhere near the happy status of "building up" immunity. There's the thoughtlessly impractical description of what "better protection" for those at higher risk would look like: "[N]ursing homes should use staff with acquired immunity" — as though there's a work force of the certifiably immune just waiting to be hired. (There is not. And even though the existence of vaccines provide hope, Trump's appalling neglect in investing in a systematic national roll-out seems consistent with the lazy assumption that "acquired immunity" would be an easier or surer option than actual preparation for mass production and distribution.) The document also made the casual assertion that "Retired people living at home should have groceries and other essentials delivered to their home. When possible, they should meet family members outside rather than inside" — as though there's a world in which "retired" people come neatly segregated in separate homes, apart from non-retired family. Indeed, even the use of the term "retired" as a cipher for age, seemed to skirt around the degree to which many people older than the age of 65 have to keep working because Social Security did not cover the costs of living even before the pandemic became a factor.

Most astonishing was this throw-away: "A comprehensive and detailed list of measures, including approaches to multi-generational households, can be implemented, and is well within the scope and capability of public health professionals." But to a hungrily contagious virus, any in-person mingling — school, bar, gym, office — is the absolute equivalent of a "multigenerational household." A young member of a "multigenerational house" who visits a gym or a school may as well be bringing her great grandparents with her. This reality of unbounded human sociality is of course, the crux of the problem, and precisely what is missing from the declaration's analysis, as well as the Trump administration's response: If there were such a "list of measures," we should have had it posted on every public billboard long ago. If the development of guidelines is "well within" the scope and capability of public health officials, there ought to have been urgent endorsement of the same from the highest national office. If there had been clearly-enunciated and vehemently endorsed protocols all along, perhaps there wouldn't have been so many lost souls drinking disinfectants and plotting to kidnap the governor of Michigan.

Instead, the declaration called for nothing more specific than "[s]imple hygiene measures, such as handwashing…" Mask-wearing was not even mentioned in the declaration. Maintaining physical distance was not mentioned. True to its libertarian origins, the plan treated the pandemic not as a biological phenomenon, but as ideology, as something that could be contained effectively by individual decision-making. That is a mindset that will take a lot of public education to reform. Within this ideological filter, the elderly and the sick were left to exercise their right to self-isolate "if they wish," configured as autonomous actors for whom rational choice is uncomplicated, a mere mental commitment to self-

This Chapter is a continuation of Chapter 36 in Volume I, "Closing Reflection: The Endless Looping of Public Health and Scientific Racism".

removal from public space. The good choice for everyone else was merely to get back out in the world, back to school, back to work, back to "normal." Not mentioned in the declaration is the Centers for Disease Control and Prevention (CDC) data showing that Black people and Latinos, disproportionately employed as low-level "essential workers," constitute 43% of all deaths from COVID-19, although they represent only 12.5% and 17% respectively of the population of the United States (Gold et al., 2020). In other words, the employment and living conditions of people of color are as important mortality risks as age. Dr. Uche Blackstock, CEO of Advancing Health Equity, observes, "It's almost as if living in a country with racism ages people … to the point where even people who are not elderly … are still susceptible to dying from this virus is in a way that's very similar to people who are elderly" (Haglage, 2020). These long-standing health disparities among racial minorities have been incalculably exacerbated by Trump's neglectful policies. Nor is this catastrophe merely one of unequal health outcomes: the fall-out includes disproportionate burdens of debt, job loss, homelessness, educational deficits, child welfare, trauma, and grief. The cascading consequences of such social disruption will be one of the greatest challenges facing the new administration.

One of the most appalling aspects of the declaration was its substitution of the term "herd immunity" for the "community spread" it was actually proposing. In epidemiology, herd immunity is defined as immunity attained by widespread programs of vaccination — typically between 60% and 80% of a population (Higgens-Dunn, 2020). That in turn depends upon the existence and availability of a scientifically efficacious vaccine that ensures immunity for a stable and significant period of time. In contrast, the term "community spread" means the promiscuous, relentless virility of infectious disease. Community spread of a deadly pathogen results in precisely the situation we face: widespread community devastation exacted by skyrocketing mortality rates attributable to said deadly pathogen.

Moreover, it is far from clear whether infection guarantees immunity, or for how long (Kelland, 2021). As has been obvious from endless spikes among partying college students and professional athletes, the young and the buff are more susceptible than the Great Barrington Declaration allows; and even if they seem to represent a lesser proportion of immediate fatalities, they may suffer disproportionately from long-term cardio-pulmonary syndromes and disabling vascular disorders. Most perniciously, the declaration is entirely complacent about the reality that COVID-19 may be spread by those with no outward or visible symptoms; its authors make no mention of the need for widespread, repeated, reliable testing of the asymptomatic.

At this writing, just after Biden's inauguration in February 2021, the United States has seen about 28 million documented infections since March 2020, with more than 500,000 deaths. As high as it is, that infection rate represents fewer than 10% of Americans. Herd immunity requires that 60%-80% of a given population be immune. Again, the Great Barrington Declaration did not propose that herd immunity happen through vaccination. Its suggestion that those levels be acquired "naturally" refers to those left standing after untold greater calamity: first, those for whom exposure does not result in death; second, those who sufficiently recover to have developed enduring antibodies; and third, those not left with long-term or permanent disability. The Great Barrington Declaration's advocacy assumed, in other words, that at least 200 million more Americans ought to just go forth, business as usual, amid the deadliest contagion in centuries — to say nothing of its exponentially spreading, rapidly mutating variants. This was the declaration's astonishing bottom line: for only at such stratospherically devastating levels of exposure, with its attendant death toll, would unvaccinated vulnerable people (what's left of them) have a hope of being protected. To get to that point without a vaccine means tolerating millions more deaths — not to mention socially destabilizing rates of grave and protracted illness. As intentional policy, this ends up not looking like "survival," even of the fittest, but instead like an intentionally induced avalanche of slaughter. For the Trump administration to have pursued such a path as a "goal" constitutes, in my opinion, a crime against humanity.

Confusions of Value

A second major challenge for the Biden administration will be the degree to which deeply contested hierarchies of legitimacy, and a jabbering bewilderment of competing sources, all laying claim to "truth" assisted the propagation of deadly confusion about basic medical science. Although the Great Barrington Declaration claimed to be endorsed by tens of thousands of medical professionals, the vetting of signatories lacked rigor (hence, endorsements from such eminent authorities as "Dr. Johnny Bananas" and "Dr. Person Fakename") (Manthorpe, 2020). In short, it is a crowd-sourced ideological tract sponsored by the American Institute of Economic Research, a libertarian umbrella group located in Great Barrington, Massachusetts, which adheres to Austrian school economic notions of methodological individualism. Major donors include Charles Koch, and the Bradley J. Madden Foundation, which has worked to evade and erode the FDA's regulatory mechanisms and processes designed to ensure health and safety protections in the approval of new drugs and vaccines. The institute's other sponsored tracts include titles like "Brazilians Should Keep Slashing Their Rainforest." Consider a recent post on the institute's website written by one of its research fellows, John Tamny (also editor of RealClearMarkets.com), entitled "Imagine If the Virus Had Never Been Detected." He asserts that:

> [T]he coronavirus is a rich man's virus…People live longer today, and they do because major healthcare advances born of wealth creation made living longer possible. We wouldn't have noticed this virus 100 years ago. We weren't rich enough. …What is most lethal to older people isn't much noticed by those who aren't old. A rapidly spreading virus was seemingly not much of a factor until politicians needlessly made it one. … The virus didn't suddenly start spreading in March of 2020 just because politicians decided it had. The likelier beginning is 2019. Early 2020 too. Life was pretty normal as a virus made its way around the world then. Politicians made it abnormal. Let's never forget the sickening carnage they can create when they find reasons to "do something."

Let me underscore that this is a post dated *February 4, 2021*.

Unsurprisingly, the glib laissez-faire recommendations of the Great Barrington Declaration were opposed by the overwhelming consensus of public health experts, including organizations like the National Institutes of Health, the Centers for Disease Control and Prevention, the World Health Organization, Britain's National Institutes of Health, the Mayo Clinic, Johns Hopkins Medical School, as well as globally regarded scientists like Drs. Anthony Fauci and Frances Collins (Medical Daily Staff, 2020).

All that said, the Great Barrington Declaration became dark reality because its free market approach was embraced at the highest levels of American governance — as well as at the lowest levels of online media circulation. This stance was aligned not only with Ayn Randian ultra-libertarianism, but also became entangled with the sovereign-citizen movement — militant anti-maskers and anti-vaxxers willing to take up arms to resist stay-at-home guidelines; belligerent anti-government souls whose extremism inspired them to descend upon legislatures in bids to ensure we may all live to die for a free-market economy.

This convergence of anti-regulatory sentiment likely means not only that the pandemic will continue to rip through certain sectors of our polity unabated for the foreseeable future, but also that the tragedy of such massive loss will imprint itself upon us as enduring collective trauma. And at a moment when fact sometimes seems to have been locked behind an inscrutable cosmic paywall, the bipartisan angst emerging from a national sense of siege should not be underestimated as its own governing force. This is an altogether dreadful moment. And dread eludes logic or law or rational discourse; it is a powerfully destabilizing force as well as powerfully directive.

Addressing Punitive Eugenic Beliefs

Among the more troubling left-overs of the Trump administration's official embrace of community spread is a certain cynical resignation on the one hand ("Gotta die one way or the other") and something like a gambler's resolve on the other ("Survival is all about your genetic lottery…"). There is something quite grim in those formulations, a transformation of the libertarian's credo of "live and let live" into the eugenicist's commitment to "live and let die." We may well worry that there is something like a death wish in this limp capitulation to nihilism.

In her book *Precarious Life: The Powers of Mourning and Violence*, philosopher Judith Butler writes of the "national melancholia" that proceeds from "disavowed mourning" for unremarked, "ungrievable deaths" (Butler, 2004). The Great Barrington Declaration reads precisely like a disavowal of mourning. We are trapped in a season of funeral after funeral after funeral — and yet even as we stand with heads bowed at multiple gravesides, there's a call from the boss telling you to just get over it and haul your butt back to work NOW. Or else You're Fired! Or you'll lose the car. Or you won't be able to stay in university. Or you can forget about health insurance. What else was it but disavowal of loss, ungrievability of death, when Dan Patrick, Lt. Governor of Texas, opined on Fox News, "Let's get back to living … And those of us that are 70-plus, we'll take care of ourselves" (Devega, 2020).

These statements are transactional in a blatantly macabre way. It puzzles me deeply, this eager swarm toward euthanasia. This profession of willingness to die for the sake of "living" is structured as sacrifice, as obedience to a higher order. This is an attitude that sees disability — including economic disability — as a social burden and an unaffordable drain. In the economically devastated period following World War I, and leading up to the full-scale grip of Nazi rule in Germany, hospitals became overwhelmed, children with birth defects became an economic burden, and poverty slowly became merged with eugenic and germophobic legal stances on behalf of the body politic. "Mercy killing" of "useless eaters" gradually became labeled as "therapy," and elimination as "treatment." Hospitals and mental institutions quietly initiated more systematized bureaucracies of killing: children deemed "unsustainable" were marked for execution by a plus-sign on their paperwork, their ultimate destiny identified as "disinfection," "cleaning," "therapy," and "treatment" (Mostert, 2002). This, of course, metastasized into the mechanics of mass murder known as The Final Solution. But I mention it here only to underscore the slow, hypnotically encroaching cultural violence when the *nation's* body is prioritized in competition with or in opposition to the stricken human body.

I wonder if the immorality of the Great Barrington Declaration would be taken as more urgently alarming if we challenged its entire framing: it gussies up a "cost-benefit" analysis of threats to the nation's economic health as the fair equivalent of human health. Without that cost-benefit frame, I think we might more readily redesignate any policy of laissez-faire do-nothing-ism as reckless and depraved endangerment of human life. To be clear, I am not, in general, an advocate of shaming or punishing those who spread communicable disease. As we saw during the AIDS crisis, there are unintended public health costs to such an approach, including hesitancy to seek medical attention. It is not easy to assign intentional fault in the middle of a pandemic: after all, we're all taking risks by going to the grocery store, we're all imperfect in our need to reach out to others, and we're all ignorant to some degree about the protocols of prevention. But as a matter of political decision-making, our leaders make choices of an entirely different dimension. Watching the White House become host to multiple super-spreader events was jaw-dropping. The presidency has power to distribute public benefits that affect the life chances of all people, and there are standards of professional conduct that must be insisted upon, that ought to have been enforced. And there is precedent for such holding-to-account. So, for example, in Massachusetts, two hospital administrators were recently charged with criminal neglect, infliction of bodily harm, and reckless endangerment of human life — they were in charge of nursing homes run by the Veterans Administration. Charged with that care, they knowingly put coronavirus patients in the same units as uninfected patients and then later actively misrepresented the numbers of stricken residents. This outbreak started one of the first major spreads in Massachusetts.

Yet, the malign behavior of these administrators was not so very different from President Trump's actions. Even after hosting unmasked balls and outbreak events that threatened national

security by sickening dozens of White House staff, Secret Service personnel, members of Congress, and of the Joint Chiefs of Staff — Trump intentionally and defiantly held subsequent rallies and town halls where thousands of maskless attendees packed together, like patients in a nursing home, like lemmings at Jonestown, all supposedly begging "to kiss me."

For at least 10 months of 2020, the degree of federal non-action was simply mind-boggling. Indeed, breaking with a 208 year tradition of non-partisanship, the editors of the *New England Journal of Medicine* published "Dying in a Leadership Vacuum," a blistering condemnation of the Trump administration's handling of the crisis: "Anyone else who recklessly squandered lives and money in this way would be suffering legal consequences."

But if what has happened thus far is indeed a crime against humanity, more worrisome still is the long-term fallout: the lethality of the virus was greatly exacerbated by months of failing to institute widespread testing while encouraging people to go about business "as normal." This habit of conduct has compounded the catastrophes we now face, for the virus, being a virus, is (predictably) mutating into various strains of yet greater contagiousness. Vaccines surely must be mass-produced as quickly as possible. But hospitals are already strained to the breaking point, people continue to lose jobs and homes, the numbers of people who are homeless continue to skyrocket, children have lost their teachers, parents, grandparents, while incarcerated people and staff in prisons and detention centers fall ill at epic rates because they are not deemed "essential." In other words, this purposefully unchecked disease has left us to navigate a treacherous and still-brewing social storm.

The American history of state-mandated, involuntary confinement of sick and individuals with disabilities isn't foremost in public discussion or anticipation right now — but we forget at our peril its invocation in the name of economic uplift during the first half of the 20th century. Growing from the American Eugenics Movement's appeals to survival of the fittest, movements to sanitize the collective national body were institutionalized in Supreme Court decisions like *Buck v. Bell*, which counseled sterilization of "those who already sap the strength of the State." (In the ultimate irony, of course, Justice Holmes wrote that the benefits of compulsory vaccination were rooted in a principle "broad enough to cover cutting the Fallopian tubes.") In other words, recent American political and juridical discourse valuing the strong over the weak is not merely grounded in economics, but contains intimations about racial, ethnic and class preference. Therefore, it would serve us well to be attentive to situations where neglectful inaction in the name of free market ideals accomplishes the same disabling end that compulsory action might have done in another era. In his 1927 *Buck v. Bell* opinion, Holmes enabled structures of thought that distinguished the "the best citizens" from the "socially inadequate" and "manifestly unfit" who may be sacrificed "to prevent our being swamped with their incompetence." The consequence was widespread state action to detain and constrain everyone from epileptics to "imbeciles," from "incorrigible" youth to wanton women to syphilitics. Today, as we watch more and more people sickening, dying, falling out of the workforce, wandering the streets, being detained in shelters, incarcerated in prisons, orphaned in institutions, camped out in tent cities and buried in potters' fields, I worry that "laissez-faire" policies have brought us to very much the same divided social end.

We should worry, too, about what might happen if the tide of public emotion turns on people who move through public space with the illness — as happened with "Typhoid Mary" Mallon. She spent the last 23 years of her life involuntarily detained in an asylum on North Brother Island in the Bronx, coalescing backlash against Irish immigrants after she persistently violated quarantine orders. I don't know if such animus might emerge from the right or the left, but I can imagine the appearance of a single demonized or intentional super-spreader becoming the justification for confinements that would draw even deeper and more irrational lines than we see now. Too much of our public health infrastructure has been transferred to or is being monitored by police rather than actual public health agencies, or policies informed by good medical practice. Consider, for example, the investment some police departments are making in drones that can take temperatures aerially of people walking down public streets. That data will be part of an overall architecture of technological surveillance that is already worrisome, but may be particularly susceptible to backlash based on blame, whether based on "bad behavior," or other configurations of biological or political danger.

If we were to remain inflected by the Great Barrington Declaration's emphasis on "personal choice" and survival-of-the-fittest as a viable response to deadly pandemic, one could foresee privately subsidized, choice-driven, even militarized health police serving as our new-age public health monitors. Since it will be a very long time before we can hope to see 80% of Americans "naturally immune," we can predict some competition for the preservation of sub-communities of such perfected bodies through enforced segregation instead. In a culture where many are yearning for, even cultivating, civil war, we might anticipate geolocation-enforced quarantine, physical segregation by algorithmically determined susceptibility based on education level, preexisting medical condition, ZIP code, gender, race, ethnicity, as well as old age. Our recent presidential election was a distressingly close one. In other words, we came very close to having the wealth of public health entities distributed according to the free-market ideological preferences of a Dr. Scott Atlas, rather than the professional public health ethics of a Dr. Anthony Fauci. As discussed in Volume I in this Chapter, some of those preferences have already been embedded in chilling forms of algorithmically-triaged resource allocation. What we have grown to tolerate in the casual demarcation of some people as economic "parasites" — as Trump called immigrants — signals that quite a few of us may be left to die as "useless" devourers of costly resources.

The Great Barrington Declaration claimed public space only for those who supposedly are brave enough, strong enough, young enough, and most of all, economically productive enough, to endure, and who could face down the invading, polluting, contaminating, economically corrupting enemy. This aesthetic fusion of viral "enemies" and economically unproductive bodies is dangerous. This cleansing of public space and assignment of

inherent value to those who remain standing (particularly without considering how lethally contagious the asymptomatic may be) is foolhardy and a recipe for chaos.

The Danger of Imaginary Bodies

One of the forces I found most mysterious in discussions of this pandemic has been the almost cult-like reverence for imaginary bodies, false icons and composited fictional entities whose ideations were mythologized, even immortalized, as greater in importance than human biological systems. Of course we humans are metaphor-machines — to one degree or another we all believe in imaginary bodies. As a lawyer, I understand the dignity accorded to "the corpus of law." As a patriot, I respect the symbolic power of embodied national values for which soldiers in wartime would lay down their lives, a precept for which Gold Star families stand in courageous sorrow. As a consumer advocate, I reject the fiction of "corporate personhood" even as I comprehend the legal creativity of its construction.

But here's what has felt so impenetrably other-worldly to me during the *annus horribilis* that was 2020: the former president of the United States was engaged in a mask-less *danse macabre*. It was nothing less than a drawn-out, hubristic flirtation with death — a pushing of scientific limits, logical limits, ethical limits. What I mean is neatly summarized by the ever-succinct, if nonsensical, Glenn Beck. Speaking of older Americans who may be statistically and immunologically more vulnerable to contracting COVID-19, he said, "Even if we all get sick, I would rather die than kill the country" (Concha, 2020).

This does not make much sense if one believes "the country" is synonymous with "we, the people" who "all get sick." As human beings, we are united in our vulnerability to COVID-19. This disaggregation of the country from its people hinted at an important conceptual shift in American identity. There was enough evidence to suppose that Beck and Trump, like the authors of the Great Barrington Declaration, were immortalizing the economy, or perhaps capitalism, as the eternal lifeblood of our nationhood. This is a perilously fragile dream in which to stick one's head — if we all die, much more than the economy will be ruined.

But my point here is to make visible the ideational bodies we have invented through such relatively common verbal gestures. Beck essentially created a golem of an embodied national Economy. He invented a mythic entity with the power to do apocalyptic battle with our fear. It is certainly understandable. COVID-19 is invisible, uncontrollably amorphous — the temptation is irresistible to "see" it as an "enemy" that can be rebuffed in some material form. Our yearning for control tempts us into conjuring various imaginary counter-forces, benevolent specters that will stand up to the virus's murderous voraciousness. At one point and for some, The Wall became the imagistic cure, as though steely barricades could block the dewy clouds of breath and death from supposedly "alien" migrants. Some prayed instead to the Winged Victory of Vaccination. Others bowed down to the Valkyries of Inherited Vitality. (In Norse mythology, Valkyrie translates as "chooser of the slain.")

Perhaps most powerfully, immunity itself has been reconfigured in some quarters as Free Radical Individualism — a brave and muscled man, frequently armed with bullet proof-vest, military grade weaponry, but, alas, no face mask. In July 2020, Vice President Pence, impersonating this kind of warrior, faced down doctors at the Mayo Clinic, radiating strength as well as his wet breath. It was, unfortunately, a colonial stance as well, whether intentional or not: if one takes a moment to acknowledge that masks are not only about protecting oneself, but also and perhaps primarily others, it ceased to look like fortitude and more like recklessness toward others.

Pence later said he did not wear masks because he wanted to look at people "eye-to-eye." Given the fact that masks do not cover the eyes, it is clear that "eye-to-eye" meant something more than just the ocular. It referred to an aesthetic, a gaze of controlled statesmanship, to be read in conjunction with firmly pressed lips and a sculpturally jutting jaw, all signifying stout resolution. With a mask obstructing that profile of nose, lips, jaw, the eyes alone become helpless, disengaged from the expressive personality of the rest of the face, beseeching and vulnerable above the anonymity of an obliterating blue medical patch. "Eye-to-eye" is a fiction of masculinity, in other words, a fantasy of the strong leader who stands bare in the face of battle. Of course it is also magical thinking, this idea of walking into the fray and dodging bullets, and emerging unscathed. It's myth-making; a way of performing miracles. Be gone coronavirus!

If we can control nothing else, we can rein in our wandering imaginations by more carefully curating our profusion of fears, and projected golems. We can choose to tell ourselves better stories. What could we come up with if we were imagining broad "social security" not for a few elderly isolates, but rather for all. If, as virologists predict, a substantial number of us can be vaccinated within a year or so, why not dream into being even-just-temporary subsidies and housing policies for all until that comes to pass? Classics scholar Paul Kosmin has written that in very ancient times of catastrophe and great death, the measure of time was stopped and, most importantly, debts were forgiven. I wonder how different would be our sense of imagined survival if we could reset the clock, and forgive the catastrophic debt ordinary people have accumulated over the past year. We need a time of pause, and amnesty, to manage the unprecedented traumas of this time. Why not dream of a plan that would keep more of us fed and housed, and truly able to choose to stay sheltered as a way of not overburdening every bit of our infrastructure with grief, with the sick, with the dying, with the dead?

In the summer of 2020, essayist Sabrina Orah Mark wrote a piece, "I'm So Tired," in *The Paris Review*, "I tell my mother about North Brother Island. 'Maybe we should buy it,' she says. 'I need somewhere to go.' What I don't tell my mother is that we have already gone somewhere. We are already in this place where the world we once knew is rushing out of us" (Mark, 2020). These words have stayed with me. If there is any consistency to what I feel, it is captured by that paragraph: There's such affecting particularity in

that vision of the external world not just changing around us, but of interior worlds "rushing out of us."

Conclusion

I have no answer for the deeply divisive fissures of race, ethnicity, and American political identity that COVID-19 has exacerbated, although I truly wish I could think my way to a happy ending. So, I read and study and reread those statistics about how ethnic minorities, Black men, and Black women are dying at higher rates. I am not an epidemiological statistic — yet I have no doubt that my body will be read against that set of abstracted data points. I, and we all, will be read as the lowest common denominator of our risk profiles at this particular moment. Not only are we no longer a "we," I am no longer an "I" in the time of coronavirus. Meanwhile, COVID-19 makes snacks of us. The fact that there may be variations in death rates based on age or exposure or pre-existing immunological compromise should not obscure the overall bottom line of its lethality. It kills infants, it kills teenagers, it kills centenarians. It kills rich and poor, Black and white, overworked doctors and buff triathletes, police and prisoners, fathers and mothers, Democrats and Republicans. At the beginning of this pandemic I hung a picture of Nelson Mandela's prison cell over my desk. He spent 25 years in that little stone room. If he could emerge strong, gentle, patient, and wise, then we surely can do months, even a few more years, waiting for vaccines and subsidence of the pandemic. I have faith there will be an end to this. I believe our lives are worth preserving. This once-great heart of a country, and the world, needs compassion, space, forgiveness, if any are to survive. We can divide ourselves up into races, and castes, and neighborhoods, and nations all we like, but to the virus — if not, alas, to us — we are one glorious, shimmering, and singular species.

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