Rethinking Health Law Architecture

Ani B. Satz[1]

1. EMORY UNIVERSITY, ATLANTA, GEORGIA, USA.

Keywords: Health Law, Health Policy, Public Health, Health Care Regulation, Public Health Emergencies

Abstract: Neither the individualistic regulatory health paradigm nor the vulnerable populations approach of public health can provide the legal structure necessary to address the most pressing problems in health care today. These approaches fail to address conflicts between individuals and populations as well as challenges to qualifying for care and are in inherent conflict with each other, sometimes within the same statute. As health concerns become more global, it is necessary to move past a vulnerable populations approach to a broader population approach that respects individual choice but does not sacrifice community health for liberty interests.

"In order to understand a problem, we must learn to take a more holistic approach."

– Charity Scott[1]

Regulatory and public health law generally are viewed as distinct. Regulatory health law, or the law regulating health care providers and institutions, focuses on the relationship between individual patients and those delivering and funding care. Meanwhile, public health law is directed at the health concerns of different populations, categorized by health care needs, geography, age, or other demographics. Our laws and related policies, government agencies, and other supporting institutions often address health concerns as if they are divided in this manner, i.e., as if some pertain to individual patients and others to populations of people. While the One Health[2] and other universal health approaches[3] challenge this divide to some degree by making health a common concern, our laws and supporting structures continue to embrace it.

This article argues that neither the individualistic regulatory health law paradigm nor the current populations approach of public health law can provide the legal structure necessary to address the most pressing health care threats today. From providing preventative health care to halting the spread of deadly pathogens, these dichotomous approaches fail to address both conflicts between individuals and populations and

Ani B. Satz, Ph.D., J.D., *is a Professor of Law and Public Health, the Director of Project on Health Law, Policy & Ethics, and an Affiliated Professor of Business at Emory University.*

The Journal of Law, Medicine & Ethics, 52 (2024): 378-387. © The Author(s), 2024. Published by Cambridge University Press on behalf of American Society of Law, Medicine & Ethics. This is an Open Access article, distributed under the terms of the Creative Commons Attribution-NonCommercial-NoDerivatives licence (http://creativecommons.org/licenses/by-nc-nd/4.0), which permits non-commercial re-use, distribution, and reproduction in any medium, provided that no alterations are made and the original article is properly cited. The written permission of Cambridge University Press must be obtained prior to any commercial use and/or adaptation of the article. DOI: 10.1017/jme.2024.103

https://doi.org/10.1017/jme.2024.103 Published online by Cambridge University Press

challenges to qualifying for care. Individual and population needs are pitted against each other in resource distribution and the creation of health care delivery mechanisms. And both approaches restrict access to care to varying degrees, with the regulatory approach focusing on insured individuals and the public health approach on "vulnerable populations."

While these approaches may overlap in the provision of preventative health care services — such as when insurance plans cover health care screenings like mammograms and colonoscopies — they are in inherent conflict with each other as paradigms for regulation, sometimes within the same statute. When this conflict occurs, regulatory health approaches typically are given funding priority, with arguably lower

This article argues that neither the individualistic regulatory health law paradigm nor the current populations approach of public health law can provide the legal structure necessary to address the most pressing health care threats today. From providing preventative health care to halting the spread of deadly pathogens, these approaches fail to address both conflicts between individuals and populations and challenges to qualifying for care. Individual and population needs are pitted against each other in resource distribution and the creation of health care delivery mechanisms. And both approaches restrict access to care to varying degrees, with the regulatory approach focusing on insured individuals and the public health approach on "vulnerable populations."

population impact.[4] For example, the Patient Protection and Affordable Care Act (ACA) — which predominantly expands health care insurance to individuals — also contains public health provisions, including those establishing the Prevention and Public Health Fund (PPHF). The PPHF supports "prevention, wellness, and public health activities including prevention research, health screenings, and initiatives, such as the Community Transformation grant program, the Education and Outreach Campaign Regarding Preventive Benefits, and immunization programs."[5] Congress intended the PPHF to be the first mandated national funding for public health[6] to avoid competition for resources between regulatory and public health initiatives, benefitting the Centers for Disease Control and Prevention (CDC), the nation's leading public health authority, as well as state and local public health authorities.[7] But the PPHF did not stabilize or strengthen the CDC's funding. After the establishment of the PPHF, the CDC's budget was reduced relative to both the National Institutes of Health (NIH) and the Centers for Medicare and Medicaid Services (CMS), which focus on individual clinical care.[8]

Over time, the CDC's budget was further reduced to support individual care. The Middle Class Tax Relief and Job Creation Act of 2012 decreased the amount of the PPHF by a total of $6.25 billion from 2013-21, in part to offset Medicare physician payments.[9] Then, in 2013, over half the PPHF's budget ($454 million) was used in implement state insurance exchanges focusing on individual care.[10] When the PPHF was reinstated to ACA levels in 2022, the CDC experienced a further funding cut of $1.3 billion.[11] A 2024 Congressional Research Service Report concluded that "CDC has not seen an overall increase in its program funding level after FY2010 [following the enactment of the ACA] when adjusting for inflation."[12]

The shift away from funding health care to address collective harms is alarming. This article posits that as health concerns become increasingly global, it is necessary to adopt a different type of health law architecture, namely, one that moves away from thinking about individuals and discrete populations towards a broader population approach. This approach must respect individual choice but not sacrifice community health for liberty interests. This article seeks to begin a discussion about the need for a new health law architecture — one that avoids the constraints of both the regulatory and public health law paradigms. The article begins by examining the false division between regulatory (individual-focused) and public health (population-focused) approaches ("the dichotomy approach"). It then addresses the harms of the dichotomy approach both to citizens and the form and function of the law. Next it examines the possibility of

The Journal of Law, Medicine & Ethics, 52 (2024): 378-387. © The Author(s), 2024. Published by Cambridge University Press on behalf of American Society of Law, Medicine & Ethics.

https://doi.org/10.1017/jme.2024.103 Published online by Cambridge University Press

a new legal approach to health that respects both individual choice and population concerns while simultaneously eschewing individual-focused and limited population approaches to health law.

The False Dichotomy

The dichotomy approach to health law, which embraces a division between individual and population focused laws and policies, is based on false distinctions. These include distinctions about health threats, access to health care services, and health care delivery and funding. Threats to health — such as contagious disease, violence, and obesity — affect individuals as well as populations. Indeed, individual medical services and public health approaches to health care may inform each other.[13] For example, public health studies guide private practice recommendations for screenings of individual children and adults for diseases and conditions such as diabetes, obesity, and depression.[14] In fact, the CDC states that one of the essential services provided by public health is to "[a]ssure an effective system that enables equitable access to the individual services and care needed to be healthy."[15]

Relatedly, health care services affecting public health may be assessed through public health entities or private providers. Traditional public health programs include those of the U.S. Public Health Service[16] as well as state and local departments of public health, which provide health care to certain at-risk populations. The goals of these public health entities are prevention and disaster response; for example, the Georgia Department of Public Health's mission is "[t]o prevent disease, injury and disability; promote health and wellbeing; and prepare for and respond to disasters."[17]

Meanwhile, the ACA requires that private health insurers and plans purchased in the Health Insurance Marketplace ("Marketplace") cover preventative health care services, including some screening and counseling services, immunizations, and other preventative care measures for women and children.[18] And as with public health corps members, medical practitioners under ACA covered-plans may be first-line responders in public health emergencies such as natural disasters and epidemics. During the emergency phase of the COVID-19 pandemic, for example, COVID vaccinations were administered by private physicians and retail pharmacists as well as departments of community health and the military.

Similarly, funding of preventative health services may be through public health programs or private insureds' plans.[19] Public health programs are funded at all levels of government, with many state and local authorities relying on federal funding from the PPHF and Health and Human Services.[20] Under the ACA, private insurers must cover designated preventative services without deductibles, co-payments, or co-insurance.[21] Plans purchased in the government's Marketplace also must fully cover these preventative services within the plan network.[22]

Further complicating the false dichotomy between public and regulatory health law approaches are inaccurate assumptions about the nature of the approaches themselves. The public health approach may be viewed as universal in nature and antithetical to individual choice.[23] It is viewed as universal in its application to individuals within a geographic population and conflicting with individual choice because population health measures require constraints on individuals' behavior. But public health as it is currently understood does not always consider an entire geographic population. Public health measures often look to prevent or address harms for those who are perceived as being at greater risk for negative health impacts, due to biological, economic, or social factors.[24] Traditionally these "at risk" or "vulnerable populations" have included individuals with disabilities, children, older adults, people from racial and ethnic minorities, and other groups.[25] These populations are viewed as uniquely susceptible to public health harms, such as those from illness and natural disasters, even though these harms may apply to all people.

Thus, the vulnerable populations view has two implications that limit the universality of the public health approach: First, it creates eligibility requirements for inclusion, e.g., some individuals with impairments may not be considered disabled and thereby fall outside special protections. Second, it fails to recognize that many vulnerabilities are part of the human condition, and relevant for everyone, as opposed to something exceptional.[26] As a result, the vulnerable populations view is broader than the regulatory approach because it considers populations instead of individuals, but it falls short of a true universal approach, which would consider all those affected by a particular health harm.

Additionally, public health measures rarely seek to constrain individual choice. While quarantine; stay-at-home orders; mandated vaccination, testing, and masking constrain civil liberties to varying degrees, they are on the extreme side of public health response. For the most part, public health measures focus on prevention within various populations "by promoting healthy lifestyles, researching disease and injury prevention, and detecting, preventing and responding to infectious diseases."[27] Promoting healthy lifestyles,

The Journal of Law, Medicine & Ethics, 52 (2024): 378-387. © The Author(s), 2024. Published by Cambridge University Press on behalf of American Society of Law, Medicine & Ethics.

https://doi.org/10.1017/jme.2024.103 Published online by Cambridge University Press

research, detection, and even most responses to infectious diseases do not involve coercive measures.

The regulatory approach also is subject to inaccurate assumptions. For example, with its focus on individuals' personal health habits and their effect on disease, the regulatory approach may be considered unresponsive to population concerns. But individual-focused health care delivery and insurance embrace prevention to improve health outcomes.[28] Individuals are assessed for health risks — biological and social — and encouraged to take preventative measures like vaccinations and screenings, institute lifestyle changes, and receive treatment to prevent the progression or spread of disease.[29] Insurance fully funds preventative health care like annual physical exams, vaccinations, and screening tests such as mammograms and offers wellness incentives.[30]

The dichotomy approach thus presents several barriers to effective legal response to public health concerns. First and foremost, it pits individual against collective rights as opposed to focusing on health goals or outcomes. The dichotomy approach creates the false perception that public health measures infringe on choice while regulatory health measures do not, even when there is a symbiotic relationship between the two. For example, during a pandemic, both private and public health institutions may mandate vaccination and masking. The dichotomy approach also results in competition for funding and divided public support. And as the COVID-19 pandemic illustrates, the dichotomy approach is easily politicized and may even be weaponized by non-governing parties to limit government response to health threats. [31] This places public health authorities in the crossfire and ultimately inhibits their ability to prevent high rates of disease spread and deaths.[32]

Second, the dichotomy approach forces a fragmented rather than a coordinated response to large-scale health threats. The dichotomy approach results in varying methods and levels of prevention and protection, rather than achieving desired health outcomes for all affected people. This both entrenches the shortcomings of the regulatory and public health law approaches and undermines the ability to respond to collective health threats. It furthers the exclusionary vulnerable populations perspective of public health, leaving some impacted people without protection. It also discounts the role that individual patient preventative care plays both in achieving public health outcomes.

Third, the dichotomy approach furthers the false perspective that we are not universally vulnerable to public health threats, which results in sporadic funding of public health measures, mostly after a threat manifests. While the ACA's PPHF was intended to provide more permanent funding to address both public health challenges and prevention research, as discussed above, a portion of the funds were diverted to support individual patient care. The federal government's emergency response of one-off large-scale funding bills to address significant health threats, such as COVID-19 and natural disasters, assume emergency response is rare. But the rise of pathogens, environmental contamination, and natural disasters suggest that there is a need to rethink the division of health care funding and delivery for continuing large-scale threats. These barriers to legal response affect disease exposure, access to health care services, funding for health initiatives, and public health emergency preparedness.

Citizen Harms

While, under the dichotomy approach, citizen interests might align for periods of time, lack of a collective goal brings conflict when interests diverge.[33] When this divergence occurs, it is typically strong individual rights that prevail over community interests. The evolving COVID-19 pandemic demonstrates the dangers of this for citizens.

From the beginning of the pandemic in 2020, emergency response was divided between public health authorities and private provider/individual response. Public health authorities focused on vaccination, social distancing, and masking, which was challenged by some individuals, even as death tolls soared and hospitals were strained. The divide between collective action and individual choice became politicized and framed in terms of individual versus collective rights. While most did not challenge public investment of billions of dollars to develop COVID-19 vaccines, once the vaccines were available, individuals began to question continued public spending on vaccine development and distribution, treatment, and disease surveillance, as well as public health mandates about vaccination, masking, and social distancing to stem disease spread. Over 1,000 cases were brought challenging COVID-era public health measures.[34]

While most public health measures withstood judicial challenge, ultimately individual choice prevailed. Public health authorities, weakened by the human and financial toll of political and legal challenge, began to loosen masking precautions. In April 2022, the CDC ended mandatory masking on public transportation.[35] Then, with the virus still surging, the end of the emergency phase of the pandemic in the U.S. was declared on May 11, 2023 (May 5th by the United Nations). Citizens lost Medicaid enrollment protections, and access to COVID-specific health care services declined.[36]

The Journal of Law, Medicine & Ethics, 52 (2024): 378-387. © The Author(s), 2024. Published by Cambridge University Press on behalf of American Society of Law, Medicine & Ethics.

https://doi.org/10.1017/jme.2024.103 Published online by Cambridge University Press

Free testing and treatment for COVID-19 was eliminated once emergency supplies were exhausted, with a bridging program only for the uninsured.[37] Private insurers limited access to the antiviral Paxlovid, which may reduce the severity of infection and protect against long COVID for all those infected, to those at risk for severe COVID.[38] Community access protections also suffered. Mandatory vaccination of federal employees, international air travelers,[39] and health care workers ended,[40] along with mandatory masking in health care facilities.[41] The CDC ended its tracking of cases and deaths.[42]

While most people hailed the announcement of the end of the COVID-19 emergency as a victory for our personal freedom, the reality is that the pandemic continues. The abandonment of public health measures unsurprisingly led to the spread of the virus and the rise of many other variants.[43] Serendipitously, the variants have not been more lethal, though that remains a possibility.[44] The variants also have not declined in lethality. COVID-19 deaths continue to be over 1,000 per week (1,785 or 1.8% of deaths as of this writing), much higher than influenza (595 or .6% of deaths).[45] COVID-19 also is the leading cause of death due to infectious disease or respiratory illness in children and young adults up to age 19 and the eighth leading cause of death in this category overall.[46]

The health of large segments of our population has been disregarded. Individuals with chronic illness, disability, and the very young and old are at substantially greater risk of serious illness and death due to the elimination of masking on public transportation and in schools, medical facilities, and grocery stores.[47] One-way masking is much less effective and often stigmatized.[48] The price of these freedoms for some is lack of health care access and civic and social participation for others.[49] For individuals with immune issues who qualify as disabled under the Americans with Disabilities Act of 1990,[50] meaningful access to public services and places of public accommodations is effectively denied, with little recourse.[51]

Failure to manage disease spread also strains our health care system, affects access to medical services for chronically ill and disabled patients, and may result in pharmaceutical and other medical supply shortages. The strain on hospitals has remained constant since the pandemic began, though to varying levels.[52] "Elective" services for chronically ill and disabled patients are affected when hospital staffing is reduced due to illness. Patients also suffer from disruption in the pharmaceutical supply chain. Following the end of the emergency stage of the pandemic, cancer drugs were in very short supply.[53]

Perhaps most troubling is the lack of preparedness for the next pandemic.[54] The end of the emergency stage of the pandemic saw reduced funding for the CDC, which had previously been reduced to shift government funding to physician payments.[55] Public health institutions are embattled and enjoy low public trust.[56] Public health responses for the collective good have been politicized.[57] And, as the next section discusses, legislatures and courts are chipping away at government emergency powers.

Perhaps most troubling is the lack of preparedness for the next pandemic. The end of the emergency stage of the pandemic saw reduced funding for the CDC, which had previously been reduced to shift government funding to physician payments. Public health institutions are embattled and enjoy low public trust. Public health responses for the collective good have been politicized. And, as the next section demonstrates, legislatures and courts are chipping away at government emergency powers.

Harms to Form and Function of Law

In addition to creating health harms, the dichotomy approach has undermined laws that support public health authorities, disrupting the ability of such authorities to achieve positive health outcomes. By creating an inherent tension between individual and collective rights, the dichotomy approach has forced legal scrutiny over any public health measure that is perceived as restricting individual liberty, even when thousands of lives are at stake. The ability of government and public health authorities to manage public health crises has been weakened by both legislatures and courts. At the federal level, this has meant curtailing Congress's Constitutional spending powers

The Journal of Law, Medicine & Ethics, 52 (2024): 378-387. © The Author(s), 2024. Published by Cambridge University Press on behalf of American Society of Law, Medicine & Ethics.

https://doi.org/10.1017/jme.2024.103 Published online by Cambridge University Press

and the actions of federal health agencies, such as the CDC.[58] At the state level, state legislatures and public health authorities have been restricted in implementing their reserved Tenth Amendment police powers to regulate public welfare and morality.[59]

Legislative response to the COVID-19 pandemic has limited the executive emergency powers of governors, state public health officials, and local health officials by hindering their ability to issue and sustain public health orders, a basic tool for prevention, protection, and health promotion.[60] For example, some states now require a notice and comment period before issuing an emergency order, undermining a timely response.[61] Other states require legislative renewal of orders and allow for legislative termination of them.[62] One state allows local orders to be less stringent than state orders, contradicting longstanding state preemption doctrine.[63] Some states now require that a public health order withstand strict scrutiny, i.e., a demonstration that it is the least restrictive means to achieve a compelling state interest.[64] Additionally, bills seek to limit the substance of public health orders by banning mask mandates as well as transportation and social gathering restrictions.[65]

Michelle Mello and Larry Gostin have framed this conflict not as one between individual rights and collective action per se, but one of balancing executive and legislative power to create democratic accountability.[66] They propose several legal changes to both empower public health officials and promote executive and legislative accountability, including expanding federal powers through the Public Health Services Act, adopting substantive standards for policies, and establishing mechanisms for legislative and public input.[67] While these changes would likely help restore the legal authority of public health authorities, they do not speak directly to the overall issues raised by the dichotomy approach itself, but rather seek a balance within it.

The dichotomy approach has created similar issues in the courts. In her new book *Constitutional Contagion: COVID, the Courts, and Public Health*, Wendy Parmet examines the role of courts in privileging individual rights over the collective good.[68] Parmet describes a historical shift that began with the autonomy individuals experienced following the development of antibiotics and culminated with the undermining of constitutionally grounded public health powers during the COVID-19 pandemic.[69]

The result of this shift is that federal courts have weighed individual rights more heavily than the compelling state interest in preserving lives.[70] The CDC was prevented, for example, from implementing mandatory vaccines or testing for large employers, which would have saved an estimated 60,000 lives.[71] Courts also struck down a number of other public health measures, including an eviction moratorium,[72] mandatory vaccines or testing for federal contractors,[73] mask mandates on public transportation,[74] and health protection protocols on cruise ships, which are especially susceptible to contagious disease spread.[75] While this shift comports with recent caselaw under the Supreme Court's "major questions doctrine" — finding that agencies do not have authority on issues of major social and economic import unless delegated by Congress[76] — it is amplified in the public health space when many lives are at stake and undermines states' police powers. Federal courts also have privileged first amendment rights of religion and speech over the compelling state interest in protecting life, striking down on first amendment grounds state laws restricting religious gatherings during the emergency stage of the COVID-19 pandemic,[77] state mandated childhood vaccines,[78] and federal attempts to stem the tide of COVID-19 misinformation on social media.[79]

To begin to address the issues raised by the dichotomy approach, it is necessary to understand how health law might respond to the evolving nature of health threats.

Increasing Collective Health Threats and Collective Response

With increasing pathogens, environmental disasters, pollution, and other health harms, health concerns are becoming more collective. Parmet documents how historically the threat of contagion — such as for smallpox or cholera — resulted in public support for laws addressing collective health concerns.[80] As a result of the collective threat, people were less resistant to public health measures, such as mandatory vaccination and quarantine, which may constrain individual liberties.[81] But despite growing collective health threats during this decade, our laws have skewed toward individual rights over community health, even when the death toll is high.[82] We are thus in a dangerous situation of legally privileging individual rights over public health at a time when doing so could have devasting health, economic, and social consequences. As the COVID-19 pandemic illustrates, a single pathogen can jeopardize global and economic stability and have profound social consequences for families and other communities.

To improve outcomes to public health threats, steps must be taken to recapture the historic public support for addressing collective health challenges that Parmet identifies. Without these changes, it is unlikely that political support will manifest to reconsider col-

The Journal of Law, Medicine & Ethics, 52 (2024): 378-387. © The Author(s), 2024. Published by Cambridge University Press on behalf of American Society of Law, Medicine & Ethics.

https://doi.org/10.1017/jme.2024.103 Published online by Cambridge University Press

lective harms and the laws that seek to address them. These steps likely include:

- **Identifying collective threats and their associated harms.** Public health authorities and independent scientists — perhaps through the formation of formal coalitions — need to clearly identify collective health threats and their potential for harm based on objective scientific evidence. Attention should be paid to environmental harms, natural disasters, and pathogens, including zoonotic diseases.
- **Communicating effectively.** Public health threats and their associated harms need to be effectively communicated by designated public health authorities and independent scientists to the public. This requires repeated, consistent, easy to follow messaging on multiple platforms that confirms to the informed consent norms for accessibility, typically around a 7th grade readability level.[83]
- **Focusing public funding and public health research.** Once collective threats to human health and their harms are identified, public funding and health research should focus on prevention of these threats and, if the threats do manifest, the best methods of detection, mitigation, and surveillance.
- **Rebuilding trust in science and public health institutions.** Efforts should be made to rebuild trust in science and public health authorities, so courts and legislatures are more likely to defer to scientific experts about necessary public health measures. Historically, courts looked to public health authorities to resolve controversial health issues.[84] Rebuilding trust in public health authorities requires effective and consistent communication about threats, mitigating measures, and accountability measures, as well as transparency in reporting. Direct scientific reporting to the public and collaboration with independent scientists also may build trust.

These steps would assist in recognizing and responding to the growing number of collective health threats and the need for unified response. This would be a significant shift from the current social-political environment but will likely be important to support a legal move away from the dichotomy approach to a new health law architecture united around a single response to collective harms. The part below provides a sketch of what that path forward might look like and seeks to begin a discussion about that possible evolution.

Toward a New Health Law

Increasing collective health threats call for a departure from the dichotomy approach to health law. The dichotomy approach is unable to respond effectively to citizen harm and enables political influence that disrupts the law and subsequently the ability of public health institutions to act. The dichotomy approach also rests on false assumptions about the reach of certain public health threats by viewing them as affecting "vulnerable populations" instead of recognizing universal vulnerability to them. Additionally, it does not provide tools to address conflicts between the collective good and individual rights.

This article begins the discussion about the need for a shift from the dichotomy approach to a legal approach that focuses on achieving health outcomes. This would entail first defining the desired outcome and then developing the path to achieve it. This path must honor individual rights to the greatest extent possible, but minor intrusions on individual rights would be justified when a significant number of lives would otherwise be lost. While dismantling the dichotomy approach would be a radical legal shift, it could occur incrementally as new law is created.

Specifically, the new health law architecture could embrace the principles that it is necessary to:

(1) Identify, define, and focus on the desired health outcomes for a certain geographic population.
(2) Identify and consider the broader geographic populations affected by health threats, i.e., local, state, national, and even global populations.
(3) Recognize shared vulnerability to most health harms and re-envision health care delivery and funding in accordance with prevention and care for whole geographic populations.
(4) Extend protections beyond vulnerable populations. This is not only a shift in degree but a shift in kind, recognizing vulnerability to health harms as part of the human condition and not as exceptional.
(5) Restore the balance between individual rights and saving lives. Preventing loss of life may entail minor intrusions on individual liberties. As assessment of disease impact should be determined by neutral public health authorities. Public health measures should be subject to continuous assessment and adjustment, if necessary, especially if they entail restrictions on individual liberties.

I offer a brief outline below of some steps that could be taken to actualize these principles and begin a shift toward focusing on collective health outcomes. The

The Journal of Law, Medicine & Ethics, 52 (2024): 378-387. © The Author(s), 2024. Published by Cambridge University Press on behalf of American Society of Law, Medicine & Ethics.

https://doi.org/10.1017/jme.2024.103 Published online by Cambridge University Press

goal of this article is to provide a sketch of what this shift might entail — more development is warranted elsewhere.

Principle (1) requires an assessment of desired collective health outcomes. These health outcomes for a population could span a broad range of ages, diseases, and conditions, with some variation between different geographic populations. Public health authorities, such as the CDC and state departments of public health, could work together to identify responses to various health threats. While these recommendations would serve only as informal guidance, ideally, they would be open to public comment to capture input from private medical practitioners and citizens. Creating such a list for purposes of public-private partnership is likely to raise public awareness about areas where collective action is required and facilitate collaboration between health care providers and the public. Public health service announcements also could be made to raise awareness of collective health concerns and proposed mitigating measures. Examples of targeted health outcomes might include the reduction of chronic diseases such as diabetes, preventable childhood diseases such as measles, certain health-harmful behaviors like nicotine use, maternal death rates, and contagious disease spread.

Once the desired health outcomes are identified and defined, public and private partnerships would be needed to coordinate care. If national in scope, these programs could be organized by HHS or its subagencies including CDC or CMS. At the state level, these partnerships could be encouraged through pilot programs funded by block grants provided by the PPHF or HHS. While some public-private coordination through PPHF and HHS block grants does currently occur, the key differences would be broad population-based initiatives coupled with greater formal oversight by designated federal or state agencies or subagencies. Initial implementation would be similar to the pilot programs of the ACA, with initiatives funded for eight financial terms. Initiatives would be subject to annual assessment for the achievement of benchmark goals after which necessary adjustments to implementation would be made.

Principle (2) requires that health threats be viewed more accurately by identifying and considering the broader populations they affect. This allows the full extent of the collective health threat to be identified and the scope of the response to be appropriate. This does not discount that subsets of the population may have more acute or varying needs, only that the collective harm requires a robust, broad-scale response to the delivery and funding of care, and the eradication of collective health harms must be measured by considering the health outcomes of all affected. Not only would this serve to address some disparities in health care, such as maternal death rates, it would better address health threats that have no geographic boundaries, such as drug resistant tuberculosis. Indeed, in some cases, international coordination may be required.

Related to this, Principle (3) requires the recognition of shared vulnerability to many health harms and the need to re-envision health care delivery and funding in accordance with prevention and care for whole geographic populations. This is where a new health law architecture will likely matter most. As new laws are passed and regulations are issued, health-supportive structures such as those affecting the delivery and funding of care, would consider many health threats to be collective or universal. This requires the abandonment of limiting concepts of disease. This leads to Principle (4), the abandonment of the public health approach to "vulnerable populations" as well as the model of care currently embraced by HHS based largely on individual provided care.[85] Health care would instead by provided by a combination of public and private partners where goals for success are measured by geographic area rather than private institution.

Finally, Principle (5) requires that our legal institutions restore the balance between individual rights and saving lives. Legislation must support state public health authorities' ability to issue public health orders, restoring states Tenth Amendment powers. Similarly, courts must return to assessing disease impact as they have historically done through deference to neutral public health authorities. Minor intrusions to individual liberties, such as mandatory masking during the emergency stage of the COVID-19 pandemic, should prevail over extensive loss of life. At the same time, public health measures should be subject to continuous assessment and adjustment by overseeing agencies, especially if they entail restrictions on individual liberties.

Conclusion

While health concerns have become more collective, law has ironically moved away from addressing public health threats towards privileging individual rights. This shift was enabled in part by our current health law architecture, which separates regulatory health law (laws primarily affecting individual patients) from public health law (laws focusing on populations). This dichotomy approach inherently pits individual rights against the collective good and is vulnerable to political influence. This article suggests that to respond to ever increasing health threats, a new health law archi-

The Journal of Law, Medicine & Ethics, 52 (2024): 378-387. © The Author(s), 2024. Published by Cambridge University Press on behalf of American Society of Law, Medicine & Ethics.

https://doi.org/10.1017/jme.2024.103 Published online by Cambridge University Press

tecture is required — one that is a holistic approach to health threats — that restores protection for the collective good while respecting individual rights. The changes outlined in this article are intended to begin the discussion of this shift.

Acknowledgements

This article is dedicated to Charity Scott, a beloved friend, mentor, and colleague, whose influential work lives on through the many people she inspired and supported. The author wishes to thank the two anonymous ASLME peer reviewers for their thoughtful suggestions.

Note

The author has no conflicts of interest to disclose.

References

1. S. Allan, S. Loue, H. Markel, and C. Scott, "Interdisciplinary Contributions to Public Health Law," *Journal of Law, Medicine & Ethics* 32, no. 4(2004): 92–96, at 94.
2. In one iteration, the One Health model seeks to expand the public health model to local, state, and even national levels and apply it across populations of humans, nonhuman animals, plants, and the environment. While it is a public health approach, it recognizes the interconnectedness of individuals.
3. See, e.g., L. F. Wiley, "Universalism, Vulnerability, and Health Justice," *UCLA Law Review* 70 (2003): 204–228 (arguing for "contextualized universalism").
4. R. R. Bovbjerg, B. A. Ormond, and T. A. Waidmann, "What Directions for Public Health under the Affordable Care Act?" Nov. 2011, *available at* <https://www.urban.org/sites/default/files/alfresco/publication-pdfs/412441-What-Directions-for-Public-Health-under-the-Affordable-Care-Act-.PDF> (last visited June 17, 2024).
5. Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111–148, 124 Stat. 119 (2010), Codified as Amended 42 U.S.C. § 18001, Title IV; *Id.* at § 300u-11(c).
6. Cong. Res. Serv., "Prevention and Public Health Fund: In Brief," Jan. 8. 2024, at 3, *available at* <https://crsreports.congress.gov/product/pdf/R/R47895> (last visited Mar. 2, 2024).
7. N. Jordan and P. Duckett, "The Affordable Care Act and Public Health," *Northwestern Public Health Law Review* 2014, *available at* <https://sites.northwestern.edu/nphr/the-affordable-care-act-and-public-health/> (last visited June 17, 2024)
8. See R. R. Bovbjerg, B. A. Ormond, and T. A. Waidmann, *supra* note 4.
9. CDC, "The Prevention and Public Health Fund," *available at* <https://www.cdc.gov/funding/documents/the-prevention-and-public-health-fund.pdf> (last visited June 17, 2024).
10. Cong. Res. Serv., *supra* note 6 at 3, 8.
11. D. McPhillips and B. Goodman, CDC Facing Major Funding Cuts, with Direct Impact on State and Local Health Departments, CNN, July 14, 2023, *available at* <https://www.cnn.com/2023/07/14/health/cdc-funding-cuts-debt-deal/index.html> (last visited June 17, 2024).
12. Cong. Res. Serv., *supra* note 6, at 4.
13. Jennifer Bard argues, for example, that public health principles should inform treatment and other response to opioid addiction. J. S. Bard, "How Public Health Informed Lawmaking Would Address the Rising Synthetic Opioid Death Toll," *Brooklyn Law Review* 87, no. 2 (2022): 657–712.
14. U.S. Preventative Services Task Force, "A & B Recommendations," *available at* <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-a-and-b-recommendations> (last visited June 17, 2024).
15. CDC, "10 Essential Services of Public Health," *available at* <https://www.cdc.gov/publichealthgateway/publichealthservices/essentialhealthservices.html> (last visited June 17, 2024).
16. HHS, "Commissioned Corps of the U.S. Public Health Service: Who We Are," *available at* <https://www.usphs.gov/about-us> (last visited June 17, 2024).
17. Georgia Dept. Pub. Health, "Mission, Values, Strategic Plan, *available at* <https://dph.georgia.gov/about-dph/commissioners-message/mission-values-strategic-plan> (last visited June 17, 2024).
18. See 42 U.S.C. § 300gg-13; see also Kaiser Family Foundation, "Preventive Services Covered by Private Health Plans under the Affordable Care Act," *available at* <https://www.kff.org/womens-health-policy/fact-sheet/preventive-services-covered-by-private-health-plans/> (last visited. June 17 , 2024).
19. See Wiley, *supra* note 3 and accompanying text.
20. 42 U.S.C. § 300u-11(c).
21. See 42 U.S.C. § 300gg-13.
22. HHS, Health Benefits & Coverage: What Marketplace Health Insurance Plans Cover, *available at* <https://www.healthcare.gov/coverage/what-marketplace-plans-cover/)> (last visited June 17, 2024).
23. See, e.g., B. Hilton, "Personal Choice vs. Public Health, Who Wins," *Medical News Today*, Jan. 12, 2022, *available at* <https://www.linkedin.com/pulse/personal-choice-vs-public-health-who-wins-bradley-hilton/> (last visited June 17, 2024) (discussing vaccination).
24. CDC, "Populations and Vulnerabilities," *available at* <https://www.cdc.gov/nceh/tracking/topics/PopulationsVulnerabilities.htm> (last visited June 17, 2024).
25. American Journal of Managed Care, "Vulnerable populations: Who are they?" Nov. 2026, *available at* <https://www.ajmc.com/view/nov06-2390ps348-s352?> (last visited June 17, 2024).
26. A.B. Satz, 'Disability, Vulnerability, and Public Health Emergencies,' in M. A. Fineman and L. Spitz, eds., *Law, Vulnerability, and the Responsive State* (Routledge: 2023).
27. CDC Foundation, "What is Public Health?" *available at* <https://www.cdcfoundation.org/what-public-health> (last visited June 17, 2024).
28. See, e.g., Agency for Healthcare Research and Quality, "Research Centers for Excellence in Clinical Preventative Services," *available at* <https://www.ahrq.gov/prevention/chronic-care/decision/research-centers/index.html> (last visited June 17, 2024)
29. *Id.*
30. 42 U.S.C. § 300gg-13.
31. See, e.g., C. Tomori et al., "Where is the 'Public' in American Public Health? Moving from Individual Responsibility to Collective Action," *eClinical Medicine*, Mar. 12, 2022, *available at* <https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(22)00071-2/fulltext> (last visited June 17, 2024) (discussing the weakening of public health institutions during the COVID pandemic due to this dichotomy).
32. M. Mello and L. Gostin, "Public Health Modernization 2.0: Rebalancing Public Health Powers and Individual Liberty in the Age of COVID-19," *Health Affairs* 42, (2023): 318-27, at 320.
33. *Id.*
34. *See* D. Bell, "Brown v. Board of Education and the Interest-Convergence Dilemma," *Harvard Law Review* 93 no. 3 (1980): 518–533 (offering a theory of interest convergence and divergence).
35. FTA, "Using Your Safety Management System (SMS) to Mitigate Infectious Disease and Respiratory Hazard Exposure," *available at* <https://www.transit.dot.gov/regulations-and-programs/safety/using-your-safety-management-system-sms-mitigate-infectious-disease> (last visited June 17, 2024).
36. HHS, Fact Sheet: End of the COVID-19 Public Health Emergency, May 9, 2023, *available at* <https://www.hhs.gov/about/news/2023/05/09/fact-sheet-end-of-the-covid-19-public-health-emergency.html> (last visited June 17, 2024).
37. *Id.*

The Journal of Law, Medicine & Ethics, 52 (2024): 378-387. © The Author(s), 2024. Published by Cambridge University Press on behalf of American Society of Law, Medicine & Ethics.

https://doi.org/10.1017/jme.2024.103 Published online by Cambridge University Press

38. K. Landman, "More Young, Healthy People Should be Getting Paxlovid when They Get Covid," Vox, Sept. 29, 2023, *available at* <https://www.vox.com/health/2023/9/29/23895613/paxlovid-young-healthy-low-risk-nirmatrelvir-ritonavir> (last visited June 17, 2024).
39. 42 C.F.R. Parts 416, 418, 441, 460, 482, 483, 484, 485, 486, 491, and 494, available at <https://public-inspection.federalregister.gov/2023-11449.pdf> (last visited Mar. 23, 2024).
40. *Id.*
41. Amer. Hosp. Ass'n, "CDC Updates Masking Guidelines for Health Care Facilities," *available at* <https://www.aha.org/news/headline/2023-05-10-cdc-updates-masking-guidelines-health-care-facilities> (last visited June 17, 2024).
42. CDC, "End of the Federal COVID-19 Public Health Emergency (PHE) Declaration," Sept. 12, 2023, *available at* <https://archive.cdc.gov/ - /details?url=https://www.cdc.gov/coronavirus/2019-ncov/your-health/end-of-phe.html> (last visited June 17, 2024).
43. CDC, COVID Data Tracker, 'Variant Proportions," *available at* <https://covid.cdc.gov/covid-data-tracker/#variant-proportions> (last visited June 17, 2024).
44. K. Katella, "Omicron, Delta, Alpha, and More: What to Know About the Coronavirus Variants," *Yale Medicine*, Sept. 1, 2023, *available at* <https://www.yalemedicine.org/news/covid-19-variants-of-concern-omicron> (last visited June 17, 2024).
45. CDC, COVID Data Tracker, *available at* <https://covid.cdc.gov/covid-data-tracker/#maps_percent-covid-deaths> (last visited June 17, 2024); CDC, Weekly U.S. Influenza Surveillance Report, *available at* <https://www.cdc.gov/flu/weekly/index.htm> (last visited June 17, 2024); *New York Times*, Coronavirus in the U.S.: Latest Map and Case Count, *available at* <https://www.nytimes.com/interactive/2021/us/covid-cases.html> (last visited June 17, 2024).
46. S. Flaxman et al., "Assessment of COVID-19 as the Underlying Cause of Death Among Children and Young People Aged 0 to 19 Years in the US," *JAMA Network*, Jan. 30, 2023, *available at* <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800816> (last visited June 17, 2024).
47. CDC, "People with Certain Medical Conditions," May 11, 2023, *available at* <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html#:~:text=Older%20adults%20are%20at%20highest,people%20ages%2018%2D29%20years> (last visited June 17, 2024).
48. L. Vogel, Is One-Way Masking Enough? *Canadian Medical Association Journal* 194, no. 19 (2022), *available at* <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9438729/> (last visited June 17, 2024).
49. C. Rhitu, "A 'Staggering' Number of People Couldn't Get Care During the Pandemic, Poll Finds," NPR, August 8, 2022, *available at* <www.npr.org/sections/health-shots/2022/08/08/1116264151/poll-1-in-5-seriously-ill-black-americans-had-a-hard-time-getting-medical-care)> (last visited June 17, 2024).
50 Americans With Disabilities Act of 1990, 42 U.S.C. § 12101 et seq. (1990).
51. See, e.g., D. Dorfman, M. Raz and Z. Berger, "Physicians' Refusal to Wear Masks to Protect Vulnerable Patients — An Ethical Dilemma for the Medical Profession," *JAMA Health Forum* 4, no. 11 (2023), *available at* <https://jamanetwork.com/journals/jama-health-forum/fullarticle/2811897> (last visited June 17, 2024) (advocating masking of providers upon request in medical facilities without a masking mandate).
52. L. C. Myers and V. X. Liu, "The COVID-19 Pandemic Strikes Again and Again and Again," *JAMA Network Open* 5, no. 3 (Mar. 9, 2022), *available at* <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2789848> (last visited June 17, 2024).
53. K. Jenei, M. P. Lythgoe, and K. N. Vokinger, "Shortages of Essential Cancer Medicines: Who is Responsible and What are the Possible Solutions?" *Lancet Oncology* 25 (2024): 23–26.
54. T. R. Frieden, M. Buissonnière and A. McClelland, "The World Must Prepare Now for The Next Pandemic," *BMJ Global Health* 6 (2021), *available at* https://gh.bmj.com/content/bmjgh/6/3/e005184.full.pdf> (last visited June 17, 2024).
55. M. Lawrence, "Super-Groups: Legal Empowerment and Public Law," *Indiana Law Journal* (forthcoming).
56. G. K. SteelFisher et al., "Trust in US Federal, State, and Local Public Health Agencies During COVID-19: Responses And Policy Implications," *Health Affairs* 42, no. 3 (2023): 328–337, *available at* <https://pubmed.ncbi.nlm.nih.gov/36877902/> (last accessed June 17, 2024).
57. *Id.*
58. U.S. Const., Art. 1, Sec. 8.
59. U.D. Const., Tenth Amend.
60. Mello and Gostin, *supra* note 32 at 321.
61. *Id.*
62. *Id.*
63. *Id.*
64. *Id.*
65. *Id.*
66. *Id.*, at 326.
67. *Id.*, at 322–25.
68. W. Parmet, *Constitutional Contagion: COVID, the Courts, and Public Health* (Cambridge: Cambridge University Press, 2023): at 37.
69. *Id.*, at 96–104.
70. *Id.*, at 104–109.
71. *Id.*, at 109–113; *National Fed. Indep. Bus. v. Occupational Safety Health Admin.*, 142 S. Ct. 661 (2022).
72. *Alabama Ass'n of Realtors v. Dept. of Health & Human Servs.*, 141 S. Ct. 2485 (2021.)
73. *Commonwealth of Kentucky et al. v. Biden et al.*, No. 21-6147, File 23a0006p.06 (6th Cir. 2023); but see Biden v. Missouri, 142 S. Ct. 647(2022) (upholding mandates for hospitals in receipt of federal funds).
74. *Health Freedom Defense Fund v. Biden*, 599 F. Supp. 3d 1144 (M.D. Fla. Apr. 18. 2022).
75. *State v. Becerra*, 544 F. Supp. 3d 1241(M.D. Fla. 2021).
76. *West Virginia v. Environmental Protection Agency*, 97 U.S. 697 (2022).
77. *Tandon v. Newsom*, 141 S. Ct. 1294 (2021).
78. *Bosarge v. Edney*, CIVIL 1:22cv233-HSO-BWR (S.D. Miss. Apr. 18, 2023)
79. *State of Missouri v. Biden*, No. 23-30445 (5th Cir. 2023) stayed by *Murthy v. Missouri* No. 23A243, 2023 WL 5968043 (S. Ct., Sept. 14, 2023).
80. Parmet, *supra* note 68, at 53.
81. *Id.*
82. *National Fed. Indep. Bus. v. Occupational Safety Health Admin.*, 142 S. Ct. 661 (2022).
83. K. B. Hadden et al., "Improving Readability of Informed Consents for Research at an Academic Medical Institution," *Journal of Clinical and Translational Science*, Dec. (2017): 361–365, *available at* <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5915809/> (last visited June 17. 2024).
84. *Bragdon v. Abbott*, 524 US 624 (1998) (looking to CDC guidelines on HIV transmission in medical settings).
85. Satz, *supra* note 26.

The Journal of Law, Medicine & Ethics, 52 (2024): 378-387. © The Author(s), 2024. Published by Cambridge University Press on behalf of American Society of Law, Medicine & Ethics.

https://doi.org/10.1017/jme.2024.103 Published online by Cambridge University Press