Two Cheers for the US Health Security Infrastructure

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I. INTRODUCTION

The COVID-19 global pandemic has rightfully caused scholars and policymakers to examine the strengths and weaknesses of the U.S. healthcare system and offer potential reforms.1 Some commentators have argued that many of the failures in our COVID-19 response were the result of our private health care system.2 In Macromedical Regulation, Professors Barak D. Richman and Steven L. Schwarz agree that the COVID-19 response in the United States illustrated weaknesses in our health system but, rather than suggest the abandonment of private health care, they argue that a shift in regulatory approach can both preserve private ownership and solve the collective action problems currently inherent in our system.3 Regulating the health care system as a system, an approach they refer to as macromedical regulation, could improve our response to systemic risks in U.S. health care.4

While Richman and Schwarz frame their proposal as a systems-based approach to U.S. healthcare regulation, they are focused not on tackling the everyday shortcomings in our system, such as health inequities and provider shortages, but on the ability of the system to respond to large-scale public health

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3 Id. at 730.

4 Id. at 732.
crises that depend on hospital-based care for treatment and containment. Their project is attempting to come up with a system of regulation that can “systematically respond to spreading health crises” and “prepare private healthcare providers for health shocks that require coordinated reallocations of resources and collective priorities.” As they explain, “we recommend a macromedical approach to regulating the hospital sector, so that individual hospitals are better prepared to handle demand surges, hospitals can coordinate with and reinforce each other as a sector, and regulators offer instrumental and regulatory leadership to mitigate surges from the next crisis.”

While there is much that could be said about our lack of a holistic approach to health resource planning and the regulation of the health system as a whole, this Comment seeks to take on the basic premise of Macromedical Regulation—the idea that we could better regulate the hospital sector to improve the ability of the sector as a whole to prepare for and respond to public health emergencies.

I begin in Part II by reviewing the existing governmental structures that are in place to prepare for and respond to public health emergencies, arguing that, while not perfect, these existing mechanisms come close to delivering some of the benefits of macromedical regulation advocated for by Richman and Schwarcz. I argue that such efforts are underappreciated and deserve the titular two cheers.

Richman and Schwarcz do not, however, envision macromedical regulation taking the form of governmental preparedness programs and structures but rather hospital regulation that seeks to improve the behavior of individual hospitals and orient it toward public health goals. In Part III of this Comment I therefore explore whether and to what extent such entity-based regulation is likely to improve systemic readiness in a meaningful and efficient manner. I conclude in Part IV by offering some suggestions for future work aimed at improving our public health emergency preparedness.

II. EXISTING HEALTH SECURITY INFRASTRUCTURE

The federal government has long recognized that it is vital to our national security to protect Americans from public health threats and has put various structures in place to try to prevent and respond to such emergencies. The Department of Health and Human Services (HHS) oversees various aspects of emergency preparedness through the Office of the Assistant Secretary for Preparedness and Response (ASPR) and the Centers for Disease Control and

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5 See id.
6 Id.
7 Id. at 776.
8 Richman & Schwarcz, supra note 2, at 730–31 (acknowledging existing governmental programs but arguing that the “primary actors” in our health system, such as hospitals and providers are better regulatory targets for controlling systemic risks).
9 42 U.S.C. § 300hh-10(b)–(c).
Prevention (CDC). In addition, within the Department of Homeland Security, the Federal Emergency Management Agency (FEMA) assists in disaster preparedness and response. There are too many federal emergency preparedness measures to list in a Comment of this length, so I simply highlight below a few such efforts that are particularly relevant to the delivery of care in a public health emergency.

At HHS, ASPR “leads the nation’s medical and public health preparedness for, response to, and recovery from disasters and public health emergencies. ASPR collaborates with hospitals, healthcare coalitions, biotech firms, community members, state, local, tribal, and territorial governments, and other partners across the country to improve readiness and response capabilities.” ASPR runs many programs related to our emergency preparedness, including the Hospital Preparedness Program (HPP) and the Strategic National Stockpile (SNS). The SNS is charged with supplementing state and local medical supplies and equipment during public health emergencies. The HPP is designed to accomplish the type of cooperation and coordination advocated for by Richman and Schwarcz. In particular, the HPP funds and supports regional collaboration that “incentivize[s] often competitive health care organizations with differing priorities and objectives to work together to prepare for, respond to, and recover from all types of threats and emergencies.”

These coalitions are designed specifically to increase the ability of healthcare organizations to plan for and react to medical surge events of the type seen during COVID-19. At a minimum, each coalition must have at least two acute-care hospitals, emergency medical services, emergency management, and public health agencies. Prior to the COVID-19 pandemic, eighty-nine percent of hospitals belonged to a healthcare coalition. In seventeen states and the District of Columbia, there was universal participation in healthcare coalitions.

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12 HHS Office of the Assistant Secretary for Preparedness and Response, HHS, https://www.phe.gov/about/aspr/Pages/default.aspx [https://perma.cc/F692-RX7T].
14 Id. § 247d-6b(a)(1).
15 See id.
17 Id.
18 See id.
20 Id. (presenting data from 2017).
21 Id.
ASPR also oversees the National Disaster Medical System (NDMS), a partnership among HHS, DHS, the Department of Veterans Affairs, and the Department of Defense, which provides medical personnel, equipment, supplies, and a system of partner hospitals to work together in the event of a medical disaster or emergency.\textsuperscript{22} The NDMS not only provides patient care in the event of an emergency or disaster but can coordinate patient transfers and mortuary assistance.\textsuperscript{23}

At CDC, the Center for Preparedness and Response has the Division of Emergency Operations that can deploy scientific experts, coordinate delivery of supplies and equipment, and provide various resources to state and local public health departments in the event of a public health emergency.\textsuperscript{24} CDC’s Division of State and Local Readiness funds preparedness activities of state and local public health systems through the Public Health Emergency Preparedness cooperative agreement and other funding.\textsuperscript{25} CDC is also involved in medical countermeasure readiness and can distribute medicines and medical supplies when necessary to respond to a large public health emergency.\textsuperscript{26}

FEMA helps to coordinate the federal government response in the event of a public health or medical disaster or emergency.\textsuperscript{27} There is an “Emergency Support Function” in place that details the structure for coordinating the federal response for such disasters or emergencies, which gives authority to the Secretary of HHS to lead the response.\textsuperscript{28}

While the federal government is uniquely positioned to oversee the United States’ response to a global pandemic, it is important to acknowledge that state governments play a significant role in emergency preparedness planning.\textsuperscript{29} The vast majority of state departments of health are accredited under either the Public Health Accreditation Board or the Emergency Management Accreditation Program, or both.\textsuperscript{30} These accreditations take into account whether a state has necessary emergency prevention and response systems in place that are staffed by qualified personnel.\textsuperscript{31} States also undertake other types
of emergency preparedness, such as laws that allow medical personnel to practice across state lines in a time of need.\textsuperscript{32}

In addition to these governmental efforts, at least two entities produce annual ratings of our health preparedness. The first, the National Health Security Preparedness Index (NHSPI), is jointly run by the Robert Wood Johnson Foundation and various academic partners with help from a national advisory committee.\textsuperscript{33} The NHSPI relies on over one hundred indicators of preparedness across six domains, including countermeasure management and healthcare delivery.\textsuperscript{34} The second index, produced by the Trust for America’s Health, uses ten select indicators and focuses on state performance in those areas.\textsuperscript{35} These indices and reports help stakeholders identify policy priorities to further improve emergency preparedness. Indeed, examining the report from the Trust for America’s Health that was published in February 2020 illustrates the apparent prescience of such reviews: “In a serious large-scale event, such as a pandemic, there will likely be shortages of beds, healthcare personnel, and equipment, requiring cooperation among healthcare entities, across systems, and across geographic borders.”\textsuperscript{36}

III. THE DIFFICULTY OF ENTITY-BASED REGULATION

Given the extensive efforts already underway to prepare for and respond to systemic health risks, one might conclude that we already have macromedical regulation in place, although not in the form envisioned by Richman and Schwarcz. Indeed, \textit{Macromedical Regulation} makes the case for entity-based regulation of the type imposed on financial actors following the 2008 financial crises that were aimed at controlling systemic risk.\textsuperscript{37} As with financial actors, they argue that hospitals—particularly for-profit hospitals—have incentives that may in fact exacerbate systemic risk rather than mitigate it.\textsuperscript{38} While their proposal for hospital regulation is not highly detailed, they do specifically suggest that imposing some type of public governance duty on hospitals may make it more likely that hospitals will contribute to the public good in the event of an emergency rather than looking out for their bottom line.\textsuperscript{39}

Yet, our experience of attempting to regulate non-profit hospitals to serve the public good illustrates the difficulties involved in this type of governance

\textsuperscript{32} See, e.g., \textit{id}.
\textsuperscript{33} \textit{About, NAT’L HEALTH SEC. PREPAREDNESS INDEX}, https://nhspi.org/about/ [https://perma.cc/Q97P-5VAZ].
\textsuperscript{35} See \textit{TR. FOR AM.’S HEALTH, supra} note 19, at 62–63.
\textsuperscript{36} \textit{Id.} at 58.
\textsuperscript{37} Richman & Schwarcz, \textit{supra} note 2, at 763.
\textsuperscript{38} \textit{Id.} at 745.
\textsuperscript{39} \textit{Id.} at 772.
reform. Non-profit hospitals (or more precisely, tax-exempt hospitals) are granted federal tax exemption on the basis that they are organized and operated for charitable purposes, specifically the promotion of health. Historically, little has been required of these hospitals to receive such tax exemption. However, in 2010 the Affordable Care Act imposed four new, specific requirements that a hospital must satisfy in order to receive tax exemption. One of these requirements was explicitly intended to require non-profit hospitals to expand their focus beyond direct patient care to include identifying and addressing the significant health needs of the community they serve, through a triennial community health needs assessment (CHNA).

While preparing a CHNA is a task different than the systemic risk mitigation at the focus of Macromedical Regulation, it shares some important features with respect to identifying needs and planning therefor. Examining the impact of the CHNA requirement is therefore helpful to determine the potential of imposing a public governance duty on for-profit hospitals.

The CHNA regulations are extensive, but for our purposes a brief summary of the basic requirements will suffice. To complete a CHNA, a hospital must define the community it serves and identify the significant health needs of that community with input from public health experts as well as people who represent the broad interests of the relevant community. The report, which must be publicly available, is required to prioritize among the identified significant health needs.

After completing a CHNA, the hospital must adopt an “implementation strategy.” The implementation strategy is a written plan that describes how the hospital plans to address each significant need identified in the CHNA or explain why the hospital does not intend to address a specific significant health need. The regulations provide that a “brief explanation” is sufficient to explain...
why a significant health need is not being addressed and offers resource constraints and a relative lack of expertise as examples of such explanations.\footnote{Id. § 1.501(r)-3(c)(3).}

While the regulations are highly detailed, hospitals enjoy significant discretion in the CHNA process. It is up to a hospital to define the relevant community and, most importantly, to decide which identified needs will receive priority.\footnote{Crossley, supra note 44, at 68.} Indeed, there is no concrete guidance regarding how priorities should be determined.\footnote{Id. at 69.} In addition, there is no requirement that a hospital actually make progress on any identified health needs, only that they report on their progress.\footnote{One commentator referred to the requirements as “superficial misdirection” lacking “genuine substance.” Zachary J. Buxton, Community Benefit 501(R)edux: An Analysis of the Patient Protection and Affordable Care Act’s Limitations Under Community Benefit Reform, 7 ST. LOUIS U. J. HEALTH L. & POL’Y 449, 451 (2014).}

Given this discretion, it is perhaps not surprising that the CHNA requirements do not appear to have caused significant shifts in non-profit hospital behavior.\footnote{See, e.g., Amy Carroll-Scott, Rosie Mae Henson, Jennifer Kolker & Jonathan Purtle, The Role of Nonprofit Hospitals in Identifying and Addressing Health Inequities in Cities, 36 HEALTH AFFS. 1102, 1102 (2017) (finding that, in a study of urban non-profit hospitals, all hospitals identified a health equity need in their community health needs assessment, but only thirty-five percent of hospitals’ implementation strategies addressed health equity and only nine percent of implementation strategies included an explicit activity to improve health equity); Geri Rosen Cramer, Simone R. Singh, Stephen Flaherty & Gary J. Young, The Progress of US Hospitals in Addressing Community Health Needs, 107 AM. J. PUB. HEALTH 255, 258 (2017) (finding, among other things, that only 54.7% of non-profit hospitals report adopting a budget for provision of services to address the needs identified in the CHNA); Cara L. Pennel, Kenneth R. McLeory, James N. Burdine, David Matarrita-Cascante & Jia Wang, Community Health Needs Assessment: Potential for Population Health Improvement, 19 POPULATION HEALTH MGMT. 178, 181–82 (2016) (finding, among other things, that over seventy percent of hospitals included in the study did not change their community benefit activities following implementation of the CHNA requirement); see also Sayeh S. Nikpay & John Z. Ayanian, Hospital Charity Care—Effects of New Community-Benefit Requirements, 373 NEW. ENG. J. MED. 1687, 1690 (2015) (noting that the CHNA requirement may result in little hospital behavior change “because hospitals are not required to change their policies in response to the findings of those assessments”); Sara Rosenbaum, David A. Kindig, Jie Bao, Maureen K. Byrnies & Colin O’Laughlin, The Value of the Nonprofit Hospital Tax Exemption Was $24.6 Billion in 2011, 34 HEALTH AFFS. 1225, 1226 (2015) (noting that, although tax-exempt hospitals are not required to align their community benefit expenditures with their community health planning activities, “a greater alignment presumably can be expected to emerge over time as communities gain more input through community health planning”); Gary J. Young, Chia-Hung Chou, Jeffrey Alexander, Shou-Yih Daniel Lee & Eli Raver, Provision of Community Benefits by Tax-Exempt U.S. Hospitals, 368 NEW. ENG. J. MED. 1519, 1519 (2013) (finding that, immediately prior to the implementation of the ACA’s CHNA requirement, tax-exempt hospitals provided most of their community benefit in the form of patient care services, with little spent on community health improvement).} After all, addressing community health needs may decrease
hospital revenue and may put hospitals at a disadvantage relative to their market competition.56

Given the experience of non-profit hospital regulation, it seems unlikely that adopting a public governance duty would improve hospitals’ emergency preparedness or public health orientation.57 There are two main weaknesses of this approach, it seems. First, requiring each hospital to separately determine, for example, what the public good requires, which supplies and equipment to stockpile, and so on, represents a huge duplication of effort and capital.58 It seems to make far more sense to centralize such planning rather than impose such requirements on thousands of individual entities.59 While there are often innovation benefits that stem from letting a thousand flowers bloom, emergency preparedness and coordinated response does not seem to be an area where such benefits would likely be realized.60

Second, it seems implausible that a general public governance duty would actually improve coordination and preparedness among hospitals, at least without specific command and control regulation.61 As we see with non-profit hospitals, if the requirement is simply to take into account public needs or the public good, a hospital has tremendous discretion in how it identifies those needs and how it seeks to address them.62 To actually change behavior with respect to emergency response or cooperation among hospitals, compulsory rules are likely needed (e.g. a hospital must have in place an emergency response system that does x, y, and z; a hospital must enter into a healthcare coalition with all other hospitals within an x-mile radius; a hospital must keep a, b, and c supplies stockpiled).63 Otherwise, hospitals will be highly likely to interpret any public governance duty in a way that suits their business model, not in a way that necessarily reflects ideal emergency preparation.64 As Richman and Schwarcz fully acknowledge, hospitals are businesses that are driven by revenue.65

Even if such prescriptive regulation is what Richman and Schwarcz envision, it seems likely that payment reform would need to drive such changes.66 For example, if we desire hospitals to engage in highly specific emergency preparation, the federal government could pay hospitals to engage

56 See Crossley, supra note 44, at 79 for a discussion of these factors (“Perhaps the most daunting impediments to hospitals devoting serious attention to community health improvement, though, lie in how hospitals are paid . . . .”).
57 See Carroll-Scott, Henson, Kolker & Purtle, supra note 55, at 1102, 1106.
58 See Crossley, supra note 44, at 74.
59 Id. at 78.
60 See id. at 103.
62 Crossley, supra note 44, at 61–62.
63 See Richman & Schwarcz, supra note 2, at 766.
64 See id. at 765–66.
65 Id. at 763–64.
66 Id. at 765–66.
in such efforts.\textsuperscript{67} This could presumably be done as a condition of Medicare participation or could be accomplished through separate disaster preparedness payments for undertaking specific actions.\textsuperscript{68} But simply ordering hospitals to engage in specific public-oriented emergency preparation activities seems likely to generate significant political opposition.

IV. CAN WE GET TO THREE CHEERS? INCORPORATING MACROMEDICAL REGULATION INTO THE U.S. HEALTH SECURITY INFRASTRUCTURE

The COVID-19 pandemic was a shock event to the U.S. healthcare system and gave us our first modern experience with a widespread global pandemic.\textsuperscript{69} While there were many success stories, and while we owe a huge debt of gratitude to all of the medical personnel, scientists, and public health professionals who worked tirelessly to respond to the crisis, it is clear that we were not perfectly prepared for this threat to our health security, despite the many governmental programs and structures described in Part II.\textsuperscript{70} Richman and Schwarcz are right to use this crisis as an opportunity to reexamine our approach to health system regulation in general and emergency preparation specifically. The time to prepare for the next health security crisis is now.\textsuperscript{71}

The core thesis of Macromedical Regulation is compelling. Few are likely to argue with the idea that healthcare regulation in the United States is piecemeal and disjointed and might be improved by a focus on the system as a whole.\textsuperscript{72} But if the ultimate aim is improving hospital-based disaster preparation and response, it seems like a prerequisite to any macromedical regulation is a careful review of the strengths and weaknesses of the extensive federal and state programs designed to prevent, prepare for, and respond to public health emergencies.\textsuperscript{73} What Richman and Schwarcz make clear is that such review should rightfully consider whether further, thoughtful regulation of hospitals and other providers might meaningfully improve our health security.

The good news is that various efforts to review our COVID-19 preparedness and response are already underway, and some responsive reforms have already been implemented.\textsuperscript{74} The Government Accountability Office (GAO) has issued

\textsuperscript{67} Id. at 765.
\textsuperscript{68} See id.
\textsuperscript{69} Richman & Schwarcz, supra note 2, at 728–29.
\textsuperscript{70} Id. at 746–48.
\textsuperscript{71} Id. at 758 (stating that historical responses to disease outbreaks were flawed in that they did not include any preparations for the next pandemic).
\textsuperscript{72} Id. at 727.
\textsuperscript{73} Id. at 742–43.
\textsuperscript{74} For example, HHS has already taken action to expand and enhance the Strategic National Stockpile’s capability to respond to a nationwide infectious disease, moving away from the prior practice of preparing for local and regional emergencies. See Expanding and Enhancing SNS Capabilities, HHS, https://www.phe.gov/about/sns/COVID/Pages/expanding-sns-capabilities.aspx [https://perma.cc/Q9TB-NFWW].
numerous reports on various aspects of the federal COVID-19 response and, to date, has made a total of seventy-two recommendations to improve the federal COVID-19 response.\textsuperscript{75} FEMA has already completed an initial review of the federal COVID-19 response and, as part of that review, has suggested specific improvements to federal pandemic response programs and structures.\textsuperscript{76} Shortly after President Biden took office, the White House issued a national strategy document which, among other things, proposed “[d]eveloping stronger institutions focused on harmonizing crisis response for emerging public health emergencies” and “[s]upporting the establishment of a mechanism to sustainably finance health security capacity.”\textsuperscript{77} States are also beginning to undertake reviews of their COVID-19 responses for similar purposes.\textsuperscript{78} The bad news is that the reviews thus far have been piecemeal, and we may not receive a clear overview of the entire response.\textsuperscript{79} That said, the United States has a history of learning from public health disasters and improving its preparedness,\textsuperscript{80} so there is reason to be hopeful.

If, after a comprehensive review of the United States’ COVID-19 response, it appears that further regulation of hospitals is warranted, I am all for a system-based approach to that regulation. The devil, as always, will be in the details. I am skeptical that soft standards, such as a general public governance duty, will do much to improve our health security, but crafting specific duties will not be an easy task, nor will determining how best to implement those duties.


\textsuperscript{78} See, e.g., Minnesota Act of June 30, 2021, ch. 12, art. 2, sec. 21 (requesting the state auditor to “conduct a special review of the state’s response to the infectious disease known as COVID-19”).

\textsuperscript{79} See supra notes 75–77 (providing examples of piecemeal reviews).