Will New Macromedical Regulation Be Prudential?

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I. INTRODUCTION

The COVID-19 pandemic potentially offers many important lessons for health policy makers. However, among the ones more likely to be neglected or downplayed are healthier skepticism about reupholstered regulatory fixes, greater modesty about our underlying political and cultural habits, and realistic prioritization in identifying what is most feasible and necessary rather than desirable but elusive. The ambitious contributions of Barak D. Richman and Steven L. Schwarzc aim at a wide array of targets, but they end up both trying to do too much, and too little.

Before traveling at full throttle down this latest regulatory highway, we first should glance ahead to the three overlapping spheres of regulatory policy history. They flash yellow caution lights and post speed limit signs—whether involving strained analogies to banking regulation, broader historical traits of regulation within the U.S. political system, or the dense web of chronic, pre-existing conditions that frustrates efforts to overhaul regulation of our health care services and operations.1 All of them should help to curb our enthusiasm, before refocusing on more necessary initial steps.

II. DIAGNOSIS AND TREATMENT OF CONTAGIOUS SYSTEMIC RISKS: HOW USEFUL IS THE BANKING MODEL?

Public policy reformers frequently argue by analogies to extend previous familiar models into adjacent territory.2 Here, the bridge from managing financial contagions to health pandemics seems partly connected but then breaks

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1 See Barak D. Richman & Steven L. Schwarzc, Macromedical Regulation, 82 OHIO ST. L.J. 727, 742 (2021).
2 See, e.g., id. at 763.
down with too much baggage and too little support. 3 Traditional crises in the financial sector in one form or another stem from escalating spikes in uncertainty over the near-term value of various financial instruments and products. 4 Contagions spread across institutions and asset classes and escalate psychologically in the absence of reliable information.5 The exponential growth of the biomedical vectors of respiratory pandemics like COVID-19 is driven by different physical forces. 6

When banks suffer demand shocks during financial crises, their depository customers are fearful of continuing to do business with them while their counterparties doubt not just their liquidity but their solvency. 7 Medical pandemic fears also involve gaps in information, but most of the change in demand volume is justified by knowledge of the quite real risks of physical contagion. 5 These rapid spreads of risk for banks and hospitals both are bad for their respective revenues and profits, but in different ways. 9 The latter are likely to suffer far more from a change in the mix, rather than the volume, of services that must be provided during pandemics like COVID-19. 10 Although this could not be assuaged fully by liquidity injections of hospital supplies over the last year, the political quirks of distribution formulas for demand-side assistance from taxpayers still worked quite well for the more profitable segments of the hospital sector. 11

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7 Richman & Schwarz, supra note 1, at 734–35.

8 See Yarovaya, Goodell & Lucey, supra note 5.

9 See Richman & Schwarz, supra note 1, at 744–45.

10 See id. at 764.

11 Even if health care regulators could not yet 3-D print hospital supplies to fill shortages, U.S. spending authorities proved able at least to enlist the Fed to print money for more rapid distribution. See Jordan Rau & Christine Spolar, Despite Covid Many Wealthy
A deeper look at the historical evolution of the Federal Reserve model for systemic risk management raises further questions about the likely pace and path of any new venture along similar lines in health care services. The former’s learning curve has been steep, bumpy, and far from complete. We should not presume that the more recent short-term fruits of emergency demand management were not offset by a previous century of greatest mis-hits in monetary and regulatory policy, including the Great Depression, the 1970s decade of unchecked inflation, the sequential savings and loan and then bank busts of the late 1980s and early 1990s, the not-so-great-moderation that popped in a tech and accounting bubble in the early 2000s, followed by the mortgage lending triggered Great Recession of 2008. Yet with each failure to see earlier what was coming later, the Fed managed to accrue more power. Given another century, it may be able to get it right, next time.

Promises that “this time it’s different” for the latest iterations of systemic risk regulation mechanisms remain untested within the financial sector, let alone for new ones involving health care arrangements. Past performance, unfortunately, may be far too predictive of future results. One underestimated
factor in the Fed’s varying focus on systemic risk involves the conflicting legislative mandates and political constituencies it must juggle. Pursuing a new extension of the Federal Reserve model into less-familiar territory seems particularly unwise when any fledgling macromedical regulator would lack the broad emergency powers accrued by the Fed over many decades.

III. INHERITED TRAITS OF REGULATORY POLITICS

Why do so many earnest plans for improved regulation of various institutions and practices turn out quite differently in practice? A host of recurring traits within the germline of much U.S. regulation provides some clues for causes. They include succumbing to mission creep, fighting the last war, adding new layers of regulation without discarding (or pruning back) older ones, lacking sustained political will to maintain sufficient surveillance and enforcement, and raiding reserves without replenishing them. Lessons learned during emergency duress about what could be regulated less, or differently, tend to be forgotten later. There are far too few Cincinnatus-like regulatory heroes, who will choose to return to their prior lives once the crises they addressed have passed. Well-honed constituencies hold on to the regulators with whom they


Although the Full Employment and Balanced Growth Act of 1978 (the Humphrey-Hawkins Act) requires the Federal Reserve to conduct monetary policy pursuant to achieving the dual national economic policy objectives of price stability and full employment, some would argue that other competing policy and political priorities include moderating long-term interest rates, furnishing an elastic currency, providing ready financing for the deficits of the government of which it is a part, and (not infrequently in recent decades) acting as manager of the risks and protector of the profits of the banking club. James A. Dorn, Myopic Monetary Policy and Presidential Power: Why Rules Matter, 39 CATO J. 577, 577–80, 585, 590 (2019); Humphrey-Hawkins Act, Pub. L. No. 95-523, 92 Stat. 1887 (1978).

See Richman & Schwarcz, supra note 1, at 739.


See BEALES ET AL., supra note 17, at 9.

See id. at 9.
can grow increasingly familiar (if not comfortable), develop partial capture
tactics, and build comparative advantages and barriers to entry against
disruptive competitors.\textsuperscript{20} As regulation matures, it tends to lag and calcify,
rather than lead and liquify.\textsuperscript{21} Chronic biases and blind spots include strong
preferences for uniformity at the national level instead of localized
customization and a far keener eye for possible market failure than government
failure.\textsuperscript{22} As memories of past emergency shortages fade, enforcement of
precautionary capacity stockpiles, let alone their financing, weakens.\textsuperscript{23} One of
the most inherent methodological handicaps in the regulators’ tool kit is the
inevitable reliance on controlling inputs rather than measuring outputs.\textsuperscript{24}
Finally, a structural bias for regulating institutions is prone to neglect how to
manage to get people and politicians to work together within them.\textsuperscript{25}

That is a long list of potential systemic risks in regulating too much, too
hastily, or too clumsily. It needs to be weighed seriously against the more
abstract promises of any new risk-reducing schemes. Further complications
arise when confronting several chronic sore spots of the health care regulation
we already experience.\textsuperscript{26}

IV. PRE-EXISTING CONDITIONS IN HEALTH POLICY

A diagnostic scan of the pathologies within past and present health policy
provides such a target-rich environment that some basic triage is necessary
upfront.\textsuperscript{27} The most feasible targets (real and misdirected) tied to macromedical
regulatory objectives include population health and its first cousin public health,
systemness, payment cross-subsidies, customer identification, stockpiling
necessary reserves, and advance planning.\textsuperscript{28} Our primary policy problems
involve poor execution and conflicting objectives rather than insufficient
regulatory instruments and planning.\textsuperscript{29} Special-interest lobbying, let alone

\begin{enumerate}[\textsuperscript{20}\textit{See id. at 7.}]
\item \textsuperscript{21} \textit{See David A. Hyman & William E. Kovacic, Why Who Does What Matters:
For a further critique of the tunnel vision and lock-in effects plaguing government regulation,
see also Hyman & Silver, supra note 17 (manuscript at 1, 10).}
\item \textsuperscript{22} \textit{See, e.g., Tyler Cowen & Eric Crampton, Introduction to MARKET FAILURE OR
SUCCESS: THE NEW DEBATE 3, 3–5 (Tyler Cowen & Eric Crampton eds., 2003).}
\item \textsuperscript{23} \textit{See Richman & Schwarz, supra note 1, at 769.}
\item \textsuperscript{24} \textit{See, e.g., WENCHE TOBIASSON, RAHMAT POUDINEH & TOORAJ JAMASB, OUTPUT-
BASED INCENTIVE REGULATION AND BENCHMARKING OF NETWORK UTILITIES 1 (May 2015).}
\item \textsuperscript{25} Am. Enter. Inst., Improving Health and Health Care: An Agenda for Reform,
YOUTUBE, at 1:35:40 (Dec. 9, 2015), https://www.youtube.com/watch?v=NQo-EeYPhEs
(remarks of Thomas Miller).
\item \textsuperscript{26} \textit{See Richman & Schwarz, supra note 1, at 741.}
\item \textsuperscript{27} \textit{See, e.g., id. at 758–60.}
\item \textsuperscript{28} \textit{See, e.g., id. at 760, 768–69.}
\item \textsuperscript{29} \textit{But see id. at 775–76.}
\end{enumerate}
regulatory capture, only explains some, but far from all, of these inherent and persistent weaknesses.

Calls for increased investment in public health and redirected focus on the maintenance and enhancement of population health are neither recent nor remarkable within U.S. health policy circles. Yet they have continued to receive lip service at best, outside of academic and other policy advocacy circles, for decades. The rhetoric of prevention and health maintenance quite simply lacks both a sufficient political constituency and an adequate revenue base (the two are not unrelated!). Although a longstanding provider-driven bias in reimbursement rates toward more acute, procedure-based treatments persists in private and public health coverage arrangements, an underappreciated factor involves a bias toward deferred just-in-time, and more intensive, medical interventions among many less-diligent patients.

Similarly, repeated recommendations for better coordination and integration of health care services and providers into more seamless systems of care often fall short in practice, face diminishing economies of scale, or produce their own new barriers to competitive entry. Increasing the size and reach of a particular health care enterprise is no guarantee that it will be managed more efficiently within a unified culture.

Focusing on hospitals as the centerpiece of macromedical regulatory concerns matches up with where the most dollars still flow, but it runs counter to broader aspirations in health policy that go beyond just ensuring that current dominant incumbents can pay their bills and stay in business. The directional trends for several decades have involved moving patients out of in-patient care as soon and as much as possible (albeit often to out-patient care tied to the same

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31 See id. at 3.
33 But see Richman & Schwartz, supra note 1, at 767–68.
34 But see id.
35 But see id. at 767–69.
However, diminishing the role of the general hospital as the all-purpose fix-it shop also has frayed the workings of various payment cross-subsidies at least nominally justified to maintain essential but money-losing services. Ensuring that each patient receives just the right care at the right time in the right setting can collide head on with macromedical sensitivities more geared to maintaining current operations. In the U.S. political economy for health care, the latter most often wins out. Even within the administered price confines of the Medicare and Medicaid programs, the halting record of substantial progress on such longstanding issues as neutral site of care payment and primary care versus specialty care reimbursement, as well as more recent echoes in pandemic assistance formulas, is telling.

Similarly, it is more revealing to examine how pre-crisis plans are implemented and executed over time and under duress. For example, in 2019, the Global Health Security Index ranked the United States first out of 196


38 See Richman & Schwarcz, supra note 1, at 729.

countries in terms of preparedness. The Secretary of Health and Human Services already had been designated under the Pandemic and All Hazards Preparation Act as the lead federal departmental authority for pandemic response. The Affordable Care Act of 2010 established the Prevention and Public Health Fund as the nation’s first permanent, annually appropriated program dedicated to improving the public health system.

In practice, these U.S. advantages in rankings and resources were outweighed by unfulfilled promises to maintain adequate inventories of necessary medical supplies. The Prevention and Public Health program not only never was fully funded, but Congress repeatedly raided its budget authority for other non-public-health purposes. All of these shortcomings are magnified by a boom-and-bust approach to macromedical challenges, in which massive funding surges during a wartime-like crisis are soon followed by the equivalent of rapid peacetime demobilization and neglect in maintaining readiness and resources in reserve.

V. REAL STARTING POINTS: A RETURN TO BASICS

Two competing strategic adages come to mind. If past efforts at improving the performance of the U.S. health care system in weathering major medical shocks have fallen so short, should we expand the role of a super-prudential microregulator? Former president and World War II supreme allied commander Dwight D. Eisenhower is credited with advising, “Whenever I run into a problem I can’t solve, I always make it bigger.” However, one also might end up with just a much larger problem, if one does not consider it in its full context, including several pre-existing conditions of the U.S. health care system noted above.

Hence, a different note of caution (uttered more rhetorically in advance than remembered in subsequent implementation) echoes from the recently deceased former U.S. Secretary of Defense in the early 2000s, Donald Rumsfeld: “You...
go to war with the army you have, not the army you might want or wish to have at a later time.”

Realistic starting points for progress, of course, reside in the remaining policy spaces between overoptimistic ambitions of clear-sighted direction from more centralized macromedical regulation and one-time reassembling and scaling up of existing authorities when the inevitable becomes unavoidable.

Rather than recreating the bureaucratic sprawl of another Department of Homeland Security-style organizational chart for pandemic planning, we should focus instead on developing a more resilient medical supply chain, facilitating quicker and more accurate health care resource information, and rebuilding political trust. Those essential challenges remain quite difficult but somewhat tractable. We will not know what we might be missing without more regular, accurate inventories of vital items for which ready offshore availability has been assumed too cavalierly. Support of continuous manufacturing techniques and coordinated purchasing of critical mass capacity needs both advance planning and persistent execution. It must overcome longstanding economic trends emphasizing outsourcing, just-in-time delivery, lean production, and globalization.

Ensuring better real-time access to early information about emerging health risks and resources to address them requires a more limited core of common data elements, uniform collection standards, and interoperability in practice rather than in theory.

Budgetary procedural safeguards can help protect longer term commitments to prudential investments to some degree, but the same political actors who enact them can find ways to bypass them later.

If we are honest about our political and cultural history in not preparing today for what we would rather avoid until tomorrow, it would be far more realistic to expect U.S. political leaders, and their followers, to hope to borrow

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48 However, there is a limited argument for reorganizing the macromedical command structure and lines of authority to some degree, such as designating and institutionalizing a new deputy national security adviser within the White House (not just another temporary task force) to coordinate pandemic and biothreat preparedness. See generally BIPARTISAN POL’Y CTR., POSITIONING AMERICA’S PUBLIC HEALTH SYSTEM FOR THE NEXT PANDEMIC (June 2021), https://bipartisanpolicy.org/download/?file=/wp-content/uploads/2021/06/Public-Health-Report_RV2.pdf [https://perma.cc/4Y7Z-T428].

49 But see Richman & Schwarz, supra note 1, at 767–69.

50 Id. at 769.

51 See, e.g., Brookings Institution, Rebuilding the U.S. Medical Supply Chain, YOUTUBE, at 18:30 (June 14, 2021), https://www.youtube.com/watch?v=vjRUZ2XpKEc (remarks of David Thompson).

52 Id. at 07:50 (remarks of Rosemary Gibson); id. at 13:00 (remarks of Spiro Gavaris).

53 See Richman & Schwarz, supra note 1, at 767–69.

54 See FARBERMAN ET AL., supra note 30, at 8.
and buy our way out belatedly and more expensively of the next set of major health risks that arrives over the horizon. *Ex post* mitigation, not prevention or containment, undoubtedly will serve as the main backstop line of defense.55

It may seem initially comforting to assume that someone at the center of the federal government will say that they are in charge and on deck, even if that pretense of knowledge is pretentious.56 However, they will need to adopt a less hospital-centric view of our health care assets and liabilities to ensure that we do not fight the most recent war all over again. Because we are far more likely to be surprised, again, by the next set of major health risks we face, a less fixed battle plan should emphasize augmenting and extending our capacity to reassemble and redirect available resources under new circumstances.57

The many failures of the initial U.S. response to the COVID-19 pandemic stemmed far more from a basic breakdown in the timely and competent functioning of a number of government officials and agencies already assigned essential responsibilities.58 Planning may be essential, but it falters when plans are not executed or procrastination, avoidance, and blame shifting prevails.59 Assigning responsibilities to monitor and assure that medical institutions are prepared for the next crisis means far less when they remain unfulfilled.60

One very vital ingredient in short supply during the COVID-19 pandemic was public trust in our leaders, and, reciprocally, political leaders’ trust in the public.61 Our civic and political institutions need rebuilding, too, so that we

55 See Richman & Schwarcz, supra note 1, at 776.


57 See Richman & Schwarcz, supra note 1, at 776–77.

58 But see id. at 742–43.

59 Or, as General Dwight Eisenhower, or British Prime Minister Winston Churchill, or “someone” once said, “Plans are worthless, but planning is everything.” *Plans Are Worthless, But Planning Is Everything*, QUOTE INVESTIGATOR, https://quoteinvestigator.com/2017/11/18/planning/ [https://perma.cc/27EK-QC4U]. The history is murky on whether this is even the original phrasing. See *No Plan Survives First Contact with the Enemy*, QUOTE INVESTIGATOR, https://quoteinvestigator.com/2021/05/04/no-plan/ [https://perma.cc/HX8U-Y998] (charting the convoluted origins of this maxim). If you prefer something even closer to the foggy chaos of the live battlefield, try the older wisdom of Prussian Field Marshal Helmuth von Moltke the Elder in 1871, which has been translated and simplified over time to “[n]o plan survives first contact with the enemy.” Id.; Steven B. Levy, *No Battle Plan Survives Contact with the Enemy*, LEXISNEXIS: LEGAL NEWSROOM (Nov. 3, 2010), https://www.lexisnexis.com/legalnewsroom/legal-business/b/the-legal-business-community-blog/posts/no-battle-plan-survives-contact-with-the-enemy [https://perma.cc/2L33-PZ7K].


respond and adapt more confidently and cooperatively to whatever we face next. They are only as strong, or as weak, as the people and leaders within them. Restoring and stockpiling some new reserves of trust and goodwill would be a good place to start before constructing the next regulatory edifice.