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### What Regulators Can Learn from Global Health Governance

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# WHAT REGULATORS CAN LEARN FROM GLOBAL HEALTH GOVERNANCE

Cary Coglianese

*The Great Pandemic of 2020 shows how much public health around the world depends on effective global and domestic governance. Yet for too long, global health governance and domestic regulatory governance have remained largely separate fields of scholarship and practice. In her book, Global Health Justice and Governance, Jennifer Prah Ruger offers scholars and practitioners of regulatory governance an excellent opportunity to see how domestic regulation shares many of the same problems, strategies, and challenges as global health governance. These commonalities reinforce how much national and subnational regulators can learn from global health governance. Drawing on insights from Prah Ruger's impressive book, I offer seven lessons for domestic regulators around the world to use to improve their performance, arguing that it is vital for regulators to see themselves as operating in a larger social environment in which they must remain agile, vigilant, and responsive to other actors and to changing circumstances.*

## INTRODUCTION

Scientists and scholars will be studying for decades the causes and implications of the COVID-19 pandemic that overwhelmed the world in 2020. For now, as the pandemic continues to rage and fatalities mount in the millions worldwide, the final extent of mortality and morbidity effects from the viral outbreak cannot be known, nor can we yet gauge the full losses from the resulting global economic dislocation. But even from the earliest days of the rampage caused by the SARS-CoV-2 virus, it has been evident how much public health effectiveness around the world depends not only on the quality of global health governance but also on the performance of domestic regulatory institutions.

The fact that the earliest cases of SARS-CoV-2 infection appeared among workers at the Huanan Seafood Wholesale Market in Wuhan, China<sup>1</sup> has brought renewed attention to the ways that viral transmission can occur when people and animals, domestic and wild, all closely come in certain food markets, particularly those in Asia.<sup>2</sup> Even if SARS-CoV-2 did not actually originate at the food market itself, its early identification there serves as a reminder of how improved local sanitation and food regulations, including those controlling trade in wild and exotic animals, can help prevent or slow the spread of pathogenic outbreaks.<sup>3</sup>

Another principal way that domestic regulation clearly affects global health stems from how nations are able to respond in the face of a virulent pathogen's transnational spread. Once the transmission of SARS-CoV-2 crossed national borders, actions by domestic regulators proved pivotal to the virus's ability to gain a foothold and spread further. Although both South Korea and the United States announced their first cases of the novel coronavirus on the same day in January 2020, the contrasting domestic regulatory responses in each country has led to vastly different patterns in viral spread.

The rate of infections in Korea began to decline within about six weeks' time, while infections skyrocketed in the United States over that same period.<sup>4</sup> Regulatory officials in South Korea immediately recognized the need for expansive testing to isolate the virus

and quickly brought together private companies to develop and administer coronavirus tests throughout the nation.<sup>5</sup> That testing allowed government authorities to isolate infected and exposed individuals, effectively containing the virus's early spread.

By contrast, officials of the U.S. Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) spent weeks following a business-as-usual plan that wasted crucial time and allowed the virus to take root in major cities across the country.<sup>6</sup> By the time the FDA finally exercised its authority to waive regulations that apply to testing in less dire circumstances, a containment strategy was too late. The spread of the virus across the United States has not only resulted in massive levels of premature mortality and other profound public health and economic effects within U.S. borders, but it also has complicated the overall battle against the global pandemic and contributed to an economic downturn around the world.

The contrasting paths taken early by South Korea and the United States—a contrast sustained even more than a year later—make evident how much global health outcomes can vitally depend on high-quality domestic regulatory responses. And yet, despite the clear connection between global health and domestic regulatory governance, the scholarship and practice of domestic regulation has remained too disconnected from the scholarship and practice of global health governance. This disconnect exists notwithstanding important similarities between governance at both the global and domestic levels—and notwithstanding the lessons that practitioners and scholars of both regulation and global governance can learn from one another.

Fortunately for regulatory scholars, the publication of Jennifer Prah Ruger's recent book, *Global Health Justice and Governance*,<sup>7</sup> provides an excellent basis for understanding the challenges of both global and domestic public health governance, and it offers an illuminating normative framework for the pursuit of global health justice. Global health governance and domestic regulatory governance share a common set of problems and common strategies for solving those problems. The common problems—chiefly, externalities, coordination challenges, and distributional inequities—often exist on different planes, with regulatory problems primarily existing within the confines of individual jurisdictions, whereas global health problems inherently transcend national boundaries. But the different planes intersect with each other, as the current COVID-19 pandemic makes plain.<sup>8</sup> Moreover, some of the same underlying issues and challenges—as well as an overall need for solutions of hard and soft power—cut across both policy planes and both fields of research.

By drawing out these connections, I seek in this essay to show what the vision of global health governance offered in Prah Ruger's remarkable book has to offer scholars and practitioners of domestic regulatory governance. Prah Ruger argues that meaningful progress in securing global health justice ultimately depends on widely accepted norms and on the coordinated efforts of a diverse array of actors and institutions—or on what she calls “shared” health governance. I suggest that much the same is needed for domestic regulatory governance to be successful. Rather than seeing regulation as just a set of rules on the books, it is more useful to view domestic regulatory governance as a social enterprise involving the interaction of a diverse range of individuals and organizations. I conclude with seven lessons that domestic regulators can learn from Prah Ruger's model of shared health governance.

## COMMON PROBLEMS

Prah Ruger begins her book presciently with accounts of previous deadly viral outbreaks: the 2013 Ebola epidemic that spread largely in Africa, and the 2003 SARS outbreak in Asia.<sup>9</sup> The international spread of contagious pathogens presents a paradigmatic example of a global health problem. Prah Ruger acknowledges that contagion is also exactly the same kind of problem that is typically used to justify domestic regulation: a negative externality. Of course, when used to justify domestic regulation, externalities are treated as failures of the private market, because the terms of individual, private transactions do not fully account for the social costs of their spillovers.<sup>10</sup> This is classically the case with pollution, and it provides the underlying justification for environmental regulation.

With respect to global pandemics, the underlying failure is only partly one of the private marketplace. Private markets are no match for a viral spread, as the prevention, management, and elimination of that spread essentially constitutes a public good. The full costs of addressing contagion vastly exceed the individual benefits to any single actor, but if positive global health outcomes are achieved, their enjoyment cannot be denied to those who fail to contribute to them.<sup>11</sup> Moreover, some of the measures needed to respond to pandemics—for example, quarantines—depend on the exercise of the kind of force which only domestic governments possess.<sup>12</sup> This is why, as Prah Ruger points out, transnational pathogenic outbreaks are *governance* problems. A global pandemic represents the failure of national governments and international organizations to coordinate and function effectively to keep a viral outbreak contained. As she puts it, “[t]he international spread of pathogenic health risks reflects global health governance failures to respond effectively and to prevent local health harms from becoming worldwide risks.”<sup>13</sup>

But externalities are not the only kind of global health problems that need attention—nor the only kind with direct parallels within the domain of regulation. Prah Ruger highlights another global health problem: the need for cross-border coordination—or what regulatory scholars sometimes call regulatory cooperation or harmonization. Such cross-border problems arise, for example, when health care institutions are integrated across nations, as in Europe. Such integration demands basically either a common set of institutional standards and rules about costs and capacities, or a system of mutual recognition of different countries’ standards.<sup>14</sup> In addition to the need to coordinate on health care delivery, a host of other problems also call for interjurisdictional cooperation, such as “counterfeit drugs,” “organ allocation and transplantation,” “overuse of antibiotics,” “medical tourism,” and “health worker migration.”<sup>15</sup> When such cross-border regulatory problems hold implications for global health, solving them necessitates both domestic regulatory responses and transnational regulatory coordination. This challenge is little different than other cross-border regulatory problems, such as those related to terrorism and money-laundering, refugees and immigration, and the safety of food, consumer, and pharmaceutical products in international trade.<sup>16</sup>

A similar type of coordination problem arises inside nations themselves. This is especially the case in countries with federal systems of government. In the United States, for example, much attention has been paid to the coordination of medical licensing schemes so that health professionals initially licensed in one state can take advantage of changes in demographics or labor market conditions and relocate to other states.<sup>17</sup> The

need for professional licensing coordination in the United States came into starker relief in response to the COVID-19 crisis. To prepare for a spike in patients and the prospect of health care workers getting sick at a time when hospitals were overwhelmed, New York City took steps in 2020 to welcome nurses and doctors from other states to fill its hospitals' staffing needs.<sup>18</sup>

A third and final type of global health problem figures prominently throughout Prah Ruger's book: inequality. This problem, too, has clear parallels within the domain of regulation.

Prah Ruger assembles empirical findings from her own research and that of others which demonstrate troubling disparities that persist in health and access to health care, both across and within countries. For example, Prah Ruger observes that:

While there has been much progress toward improving global health outcomes over the past several decades, global inequalities in adult and child mortality remain extreme; the gap is far from being closed, and the distribution of health burdens and benefits is drastically unequal. Mortality gaps between the richest and poorest countries are wide. Worldwide 99 percent of maternal deaths occur in developing countries.<sup>19</sup>

Even within developed countries such as the United States, differences in health outcomes and standards of living can be extreme. Life expectancy, Prah Ruger reports, is twenty years greater on average in urban areas of Colorado than in North and South Dakota.<sup>20</sup> Residents in downtown Chicago live an average of sixteen years longer than their principally Black and Hispanic neighbors in the city's south side.<sup>21</sup>

Despite the existence of such health disparities within a single country's borders, it may be at first glance unclear the extent to which this inequality is fully a *regulatory* problem. Regulation has not been typically viewed as the principal domestic policy tool used to respond to societal inequality; taxation and social services tend to handle most of the distributional work from the standpoint of domestic policy.<sup>22</sup> But laws and rules do make up an essential part of the policy toolkit that makes any tax or spending program work. Moreover, concerns about inequality do directly undergird many areas of regulation. Employment discrimination regulation and other civil rights laws expressly aim at social inequities produced by racial and gender biases.<sup>23</sup> Environmental regulators are aware that pollution patterns contribute to disparate health outcomes along racial and socioeconomic lines, and, as a result, these regulators have sometimes developed programs or set enforcement priorities in an attempt to address environmental injustices.<sup>24</sup> In these and other ways, the problem of inequality remains a matter of great concern in the realm of both global health governance and domestic regulation.

## COMMON SOLUTIONS

Despite sharing a common set of problems with global health governance (externalities, cross-border coordination, and distributional inequities), regulatory governance might seem otherwise unrelated to global health governance. After all, regulation is associated with governmental entities that issue rules and rely on hard sanctions to enforce them—a model of power more compatible with the state-dominated world of what Prah Ruger calls *international* health governance. Prah Ruger makes clear

that international health governance, sometimes labeled “Westphalian” after the 1648 Peace of Westphalia treaties, centered around nation-states and their sovereignty.<sup>25</sup> That model of governance might have applied in the past, but it contrasts with what has become a system of *global* health governance since around the middle of the Twentieth Century.<sup>26</sup>

This newer system of global health governance still accommodates the older Westphalian system—indeed, Prah Ruger acknowledges the continued “primacy of states”<sup>27</sup> even today—but global health governance is not exclusively dominated by state actors. Instead, it reflects the reality that a multiplicity of non-state actors also shapes health outcomes and patterns around the world. Prah Ruger observes that the behaviors of these various actors are “uncoordinated,”<sup>28</sup> “diffuse[, and] non-hierarchical.”<sup>29</sup> They “lack any clear structure” because global health governance “does not clearly delineate roles for states, UN organizations, international organizations, civil society organizations, and public-private partnerships.”<sup>30</sup> The chaotic state of affairs makes global governance something closer to a Hobbesian state of nature: “Fierce competition among actors and priorities results in end runs around national governments and the UN system.”<sup>31</sup> As a result, it is more accurate to describe global health governance as “increasingly political and decreasingly technical and scientific.”<sup>32</sup>

Perhaps surprisingly, much the same can be said of domestic regulatory governance. Over the last several decades, both the practice and the study of regulation has shifted toward recognition of its more highly fragmented and contested state of affairs, replete with multiple public and private actors. No longer is regulation viewed as merely a formalistic application of binding rules imposed by government on private industry. Today, governments around the world deploy a mix of tools, and binding rules are only one of many.<sup>33</sup> The work of regulators encompasses extensive use of public outreach efforts, information campaigns, guidance statements, and technical assistance. Voluntary recognition or rewards programs are now quite common,<sup>34</sup> and public regulators take great interest in developing public-private partnerships in an effort to achieve regulatory goals.<sup>35</sup>

Government regulators’ blending of binding legal rules with a variety of non-binding strategies is possible due to the diverse nongovernmental actors that make up the social environment within which domestic regulatory governance operates. Nongovernmental forms of regulatory governance include self-regulatory schemes, such as the chemical industry’s Responsible Care program<sup>36</sup> and the nuclear power industry’s Institute of Nuclear Power Operations.<sup>37</sup> An extensive array of nongovernmental standards today are produced by industry groups and national and international standard-setting bodies, such as Underwriter’s Laboratories, the ASTM International, and the International Organization of Standardization.<sup>38</sup> Regulators rely on these nongovernmental standards either to substitute for or complement binding governmental rules. And, not infrequently, these nongovernmental standards become adopted as binding governmental rules through a process known as incorporation by reference.<sup>39</sup>

Just as global health governance is more than just a Westphalian world of nation-states, so too is regulatory governance about much more than a narrow realm of rules. Regulators, after all, are seeking to shape individual and organizational behavior in ways that solve problems or improve social or economic conditions. Both regulators and regulatory scholars thus understand that formal regulatory law is only one factor affecting relevant behavior. Other forces also can be used to achieve regulatory goals.<sup>40</sup> Indeed, a widely accepted framework views the behavior of regulated businesses as shaped by

“three ‘licenses’”—a regulatory license (the formal law and its enforcement), an economic license (business imperatives), and a social license (community pressures and social norms).<sup>41</sup> Both regulators and the businesses they oversee recognize the power of the so-called social license in shaping firms’ behavior. The social license can be more demanding than either of the other licenses—even to the point that, within certain sectors and with respect to certain regulations, businesses will go beyond merely complying with their regulatory licenses and invest in costly measures that demonstrate their commitment to various environmental and social values, or what is sometimes referred to as corporate social responsibility.<sup>42</sup>

In the end, domestic regulatory governance has much more in common with global health governance than it might first seem, even though these commonalities operate at different scales and within a different geographic scope. The types of problems that motivate global health governance also motivate regulatory governance. And just as global health governance comprises a broad, even eclectic, “set of standards, institutions, rules, norms, and regulations,”<sup>43</sup> so too does regulatory governance comprise a pluralistic and intersecting set of internal and external behavioral drivers, as well as governmental and nongovernmental standards. As Prah Ruger shows, “[b]oth state and non-state actors are important instruments in achieving global health justice,”<sup>44</sup> and so too are both state and non-state actors pivotal to the efficacy of regulatory governance in delivering public health within the confines of a particular national or subnational jurisdiction.

## COMMON CHALLENGES

As a result of these similarities in both problems and solutions, it should come as little surprise that many of the challenges that “vex” global health governance also often vex regulatory governance. Prah Ruger describes an array of challenges at the global level: “hyperpluralism and fragmentation”; “incoherence, disorder, and inefficiency”; “blurred lines of responsibility”; “actors with divergent interests”; controversial “normative principles and processes”; policy uncertainties and shortage of data and “analysis of ... problems”; power imbalances that lead some actors to exert “excessive political influence” of self-interested actors; and a lack of “credible compliance and dispute resolution mechanisms.”<sup>45</sup>

This list describes astonishingly well the challenges that confront domestic regulators in advanced pluralist societies. Regulators in the United States and Europe, for example, find themselves increasingly operating in an environment of growing inequality, polarization, and adversarialism.<sup>46</sup> The U.S. governing system in particular is said to lack “socially desirable incentives; rational selection of ends and means; accurate, unbiased, up-to-date information; the capacity to adapt promptly and flexibly to a changing policy environment; credibility to those actors whose expectations and responses will ultimately determine policy success or failure; and a bureaucracy that can manage and implement policies effectively in the real world.”<sup>47</sup> The rise of the internet and social media has made sleepy backwaters of regulatory policy-making much more contentious, and the emergence of populism and still uglier forms of nationalism only add to today’s challenges.<sup>48</sup> One need only look to ethnic conflicts, civil strife, and social movements as varied as Brexit, the Tea Party, Yellow Vests, and the Arab Spring to see the disruptive politics confronting domestic governance.

When Prah Ruger observes that *shared* health governance—her aspirational but also positive or descriptive account of global health governance—depends largely on voluntary acceptance of norms, she could be writing about domestic regulatory governance as well. As she puts it, governance at the global level depends on an “overarching principle [of] voluntary compliance rising from common values, shared norms, and both substantive and procedural legitimacy.”<sup>49</sup> Shared health governance, she writes, “relies on persuasion, education, and social movements to shape positive moral norms.”<sup>50</sup> This is not qualitatively distinct from domestic regulatory governance. Admittedly, domestic regulation does afford the possibility of inducing behavioral compliance by way of punitive sanctions that transnational institutions cannot mete out to enforce international norms. Even though the importance of such enforcement power should not be discounted, regulators also aspire to solve problems rather than just impose penalties for their own sake.<sup>51</sup> It marks success if regulators reach a point where threats and sanctions are no longer needed.

At the domestic level, much regulatory compliance is effectively voluntary. This fact probably cannot be overstated. Domestic regulators rarely have oversight officers physically present at regulated industrial operations to observe them on a continuous basis. The number of inspectors needed to visit each regulated entity in any country’s economy, even just on annual basis, would likely well exceed available public resources. As a result, most regulated businesses, most of the time, escape any direct oversight of their compliance with regulation. And yet, compliance still occurs. Regulatory authorities depend on widely shared norms about the legitimacy of the law to induce compliance.<sup>52</sup> As Peter Schuck has written, “the mass compliance necessary for effective policy implementation depends far less upon episodic agency enforcement than upon a fragile condition: citizens’ internal sense of the rectitude, competence, and legitimacy of the law and of the officials who administer it.”<sup>53</sup>

In the end, the differences between global governance challenges and domestic governance challenges are much less profound than they might first seem—at least as would seem apparent from the much too separated worlds that global governance scholars and regulatory governance scholars tend to inhabit. These differences between levels of governance are more a matter of degree than of kind. They are differences also in the units of analysis emphasized: individuals and firms for regulatory governance; nation-states and international actors for global governance. But they are not so different in terms of their basic underlying problems, solutions, and challenges.

At any level, governance is about securing order, changing behavior, and managing disputes—all in an ever-changing world of competing interests and ideas. As such, governance is never easy, nor has it yet proven entirely satisfactory on any level.<sup>54</sup> Still, once a greater number of scholars and policy actors recognize the commonalities between the realms of global and domestic governance, it should then become easier to learn lessons from each realm.

## **LESSONS FOR REGULATORY GOVERNANCE**

A number of leading regulatory scholars—John Braithwaite, Susan Rose-Ackerman, Charles Sabel, and Richard Stewart, to name a few—already have recognized commonalities between the domestic and global realms of governance and made important contributions to understanding governance of both kinds. But too many other

regulatory scholars tend toward a more limited focus solely on governance at the domestic level, passing up opportunities to learn from research on global governance. In addition to the much-too-separate realms inhabited by scholars, regulatory decision-makers could also learn much from those who study global governance. For anyone who tills mainly in domestic regulatory fields, Prah Ruger's *Global Health Justice and Governance* inspires valuable lessons about the priorities and principles of high-quality domestic regulation.

At least seven lessons for national and subnational regulators can be gleaned from Prah Ruger's account of global health governance and especially from her case for a "shared" governance system grounded ultimately in a commonly accepted set of values and norms which intrinsically motivate the action needed to deliver global health justice.<sup>55</sup> Given the necessary interdependence that Prah Ruger rightly recognizes exists between global health governance and domestic regulatory governance, domestic regulators have much they can learn from her illumination of the governance challenges associated with the quest for global health justice. Greater consideration of the following lessons could help promote not only improved health conditions at the national level, but also an improved health justice at the global level.<sup>56</sup>

1. *Pay attention to the distribution of regulatory outcomes and not merely their aggregate levels.*

Prah Ruger argues throughout her book for improvements in global health justice in distributional terms. She is rightly troubled by today's gross disparities in both health outcomes and available health care resources. Using the level of health needed to sustain human flourishing as a benchmark, she emphasizes how people in different parts of the world lack even this basic floor.<sup>57</sup> Public health officials around the world thus need to reduce shortfalls or gaps between that optimal floor and present-day reality.<sup>58</sup> As she explains, "the health goals of a just society are to ensure all individuals have the ability to be healthy."<sup>59</sup> This approach does not demand that everyone in fact achieve identical levels of health. Nor does it deny the importance of efficiency and other aggregate measures of human welfare and development. After all, economic development provides an important pathway toward health justice. But justice does necessitate global movement toward minimizing what Prah Ruger terms "shortfall inequality"—that gap between needs and reality.<sup>60</sup> It means reducing the number of people who lack basic health resources and acceptably safe conditions in which to work and live.

Domestic regulators and regulatory scholars have an obvious role to play making progress toward health justice. Building codes, environmental regulations, and workplace health and safety standards all purport to deliver benefits that promote healthy conditions for the overall public, including those with the least resources. Yet regulators too seldom see themselves as in the business of promoting equality—whether of health or of any other regulatory goal. The principal metric for both regulatory design and evaluation has long tended to focus on aggregate effects—whether benefits overall justify costs overall.<sup>61</sup> Under the Kaldor-Hicks efficiency framework, as long as benefits exceed costs, a regulatory policy will be deemed successful. Seldom do regulators concern themselves with explicitly assessing how regulations' benefits and costs are distributed across different segments of society. Even when regulatory agencies are supposed to consider the "distributive impacts" of their regulations,<sup>62</sup> in practice they rarely conduct any systematic analysis of the distribution of regulatory costs and benefits.<sup>63</sup>

This lack of attention may stem, at least in part, from some uncertainty about exactly how to factor the distribution of impacts into any specific regulatory decision. How much regressivity in the distribution of regulatory impacts ought to be tolerated? Does the tolerable level depend on the size of the overall net benefits of the regulation? Perhaps if a new regulation results in benefits vastly outweighing its costs, then it should not matter if those with greater income or wealth in society are shown to benefit to a somewhat greater degree. To date, though, no common professional agreement has yet to be reached over what might constitute a tolerable level of regressivity in regulatory impacts nor over how tradeoffs between overall welfare and equity should be made.<sup>64</sup> Certainly nothing like the clear benchmark offered by the Kaldor-Hicks framework for efficiency exists for assessing the distribution of regulatory impacts.

Even if such a benchmark did exist, there would still be a question of whether regulation is the appropriate policy arena within which to pursue distributional justice. Perhaps if a market failure exists and regulation fixes it, then that should be the end of the analysis and any resulting inequities created by the regulation would be better addressed through other programs and policies specifically aimed at redistribution.<sup>65</sup> But even if that is so, the need for distributional analyses of regulatory impacts would still remain important. For one thing, even if regulators should mainly focus on aggregate net benefits, the possibility that a particular regulation or regulatory program might on occasion result in highly skewed regulatory impacts that severely harm already disadvantaged individuals in society should at least lead regulators to adjust their policy actions in those instances to reduce those harms. Furthermore, the mere step of identifying the distribution of regulatory effects could influence support for other social policies to offset the inequities. If regulators do little to estimate and disclose publicly the distribution of impacts, then tax or spending policies to offset regulations' distributional inequities may be less likely ever to be pursued.<sup>66</sup> It would be valuable for domestic regulators to heed the message in Prah Ruger's book by doing more to emphasize equality concerns in regulatory governance.

## 2. *Use hard law strategically to reinforce soft law.*

Prah Ruger's vision for "shared health governance" driven by widely accepted norms seems the apotheosis of soft power.<sup>67</sup> Still, Prah Ruger recognizes that the full attainment of shared health governance cannot magically arise on its own accord. It depends on an iterated set of interactions between global health institutions and nation-states. In this regard, she acknowledges that "sanctions, incentives, and punishments can be helpful."<sup>68</sup> Global actors can provide incentives for state action, and states in turn can then build up their own capacities to deliver on the promise health justice. Ideally, in the end, such iteration and progression lead to an equilibrium in which global and national actors follow shared norms to carry out responsibilities in ways that rely on their respective comparative advantages.<sup>69</sup>

This model of shared health governance for the achievement of global health justice mirrors an excellent strategy for domestic regulation. Regulators will rarely, if ever, possess the resources needed to oversee all the actions of all the individuals and entities whose behavior regulation seeks to affect. As a result, regulatory organizations need to deploy their scarce resources strategically, trying to maximize public value from the steps that they are able to take.<sup>70</sup> That means recognizing that punitive action is

costly—both in what it takes to document and enforce violations, but also in the potential for making regulation seem unreasonable and sparking resistance by regulated actors.<sup>71</sup> Regulators must use their limited enforcement resources wisely, such as by targeting actors that pose the greatest risks to society.

When they approach regulatory encounters in a responsive fashion—that is, by first seeking to treat legal violations as problems to solve, and only later escalating punitively in response to regulated entities' recalcitrance and resistance—regulators often seek to reinforce social norms, even if they do not necessarily substitute completely for them.<sup>72</sup> They frequently see their role not as a lone sheriff in town, but rather as an integral part of a larger social system shaping private behavior.<sup>73</sup> Especially in the face of limited capacities for monitoring and oversight, they need to use their resources to complement, reinforce, and leverage private motivations and non-legal norms that can support socially optimal behavior.<sup>74</sup>

### *3. Preserve and strengthen institutional trust and legitimacy.*

Social norms also affect the levels of public support, trust, and legitimacy that surround both domestic and international governing institutions. Prah Ruger acknowledges a set of process-oriented norms, such as those calling for institutions to exhibit neutral decision-making, transparency, and public participation.<sup>75</sup> She also importantly recognizes a relationship between legitimacy and the substantive performance of any governing institution. This relationship manifests itself in two ways.<sup>76</sup> First, an institution's substantive performance improves the degree of trust and legitimacy it earns from the public. Institutions that fail to deliver on the promise of improved health outcomes and equity will hardly engender much confidence, while those that deliver consistently high levels of substantive success will gain greater trust. Second, by adhering to fair, open, and accountable procedures, institutions build and maintain trust and legitimacy that in turn strengthens their ability to achieve substantive success. As Prah Ruger explains, global health governance “needs impartial institutions that engender trust and legitimacy” because “[o]nly this kind of institution can inspire acceptance and adherence.”<sup>77</sup>

This is also true for domestic regulators. At the same time that these national and subnational institutions exist to deliver substantive regulatory outcomes, their leaders also will do well to attend to “perceptual outcomes,” such as public confidence, trust, and legitimacy.<sup>78</sup> These perceptual outcomes amount to resources that are perhaps even more valuable than fiscal resources in terms of a regulatory body's ability to achieve its mission. Trust and legitimacy can affect the level of voluntary compliance with regulations. They also help make it more likely that the regulatory body will receive the political support and budgetary outlays essential for substantive success.

Perhaps nowhere has the importance of perceptual resources been better documented than with Dan Carpenter's detailed history of the U.S. FDA.<sup>79</sup> Carpenter demonstrates how the agency benefited for many decades from its ability to inculcate a reputation for scientific rigor and regulatory integrity. Of course, in more recent years, the FDA has struggled at times to live up to the stellar regulatory reputation it once held, encountering criticism over delays in its drug approval process and controversies over perceived regulatory oversteps, such as with respect to its assertion of authority to regulate tobacco in the 1990s. Most recently, the agency's perceived initial slowness to

respond to the CoV-2 outbreak has put a critical spotlight on the FDA, and it continues to struggle to find an appropriate balance with respect to regulatory oversight of coronavirus testing, treatment, and vaccines.

In fairness, of course, the current pandemic puts an enormous strain on nearly every institution. But the pandemic also demonstrates how vital it is, in times of crisis, for pivotal domestic regulators to be able to draw upon a reservoir of legitimacy and trust. In the end, the path toward the restoration of the economy following the Great Pandemic of 2020 will likely depend on whether members of the public have confidence that their governmental institutions will adequately ensure their health and safety if they return to normal life.<sup>80</sup> Pandemics make crystal clear what is also true in normal times: effective governance depends on trust—and the best regulators always seek to earn that trust, both through how they act and by what they achieve.<sup>81</sup>

#### 4. *Be vigilant and dynamic in the face of changing behavior and conditions.*

The world is constantly changing, with many moving parts interacting in different ways over time. As a result, to be effective, governance must remain a continuously active undertaking. Prah Ruger wisely warns against “indecisiveness”<sup>82</sup> and a “fail[ure] to act.”<sup>83</sup> She urges a shared health governance that “is dynamic, addressing current and future challenges.”<sup>84</sup>

In addition, Prah Ruger illustrates the dire consequences that can arise from inaction by recounting the 2007 fiasco involving Atlanta lawyer Andrew Speaker, who tested positive for a highly resistant strain of tuberculosis. Due to feeble efforts by public health officials in the state of Georgia, Speaker managed to take multiple international flights after having been diagnosed with tuberculosis and warned not to travel. Prah Ruger places much of the fault for the resulting public health dangers on the shoulders of the state of Georgia (ironically, where the U.S. CDC is headquartered) due to the state’s failure to provide “adequate surveillance, reporting, intervention, and personnel training.”<sup>85</sup>

Prah Ruger’s example shows what can happen when domestic regulators succumb to “dithering” in the face of new risks or changing circumstances.<sup>86</sup> More generally, the example provides a still broader lesson for regulators of all kinds never to treat the world as static. Economic and social conditions are constantly in flux; new technologies and new risks are regularly emerging. Regulation will not succeed if it is viewed a matter of just putting rules on the books. It must be agile and responsive.

Effective regulation requires active “obligation management”—adding new requirements, modifying or lifting existing ones, monitoring conditions and overseeing compliance, and variously cajoling and threatening as needed.<sup>87</sup> Regulatory effectiveness requires staying vigilant as to how regulated entities adapt in response to regulatory requirements. Even after a regulation is adopted, regulated entities are still likely to have interests at odds with the purposes of the regulation and therefore they will still have self-interested reasons to try to defeat or circumvent those purposes.<sup>88</sup> “Agility” and “adaptability” may not be the kinds of adjectives that most people immediately associate with regulation, but many regulatory problems could be avoided with greater responsiveness by the leaders of regulatory organizations in the face of new problems or changes in industry behavior.<sup>89</sup>

### 5. *Coordinate with other actors and institutions.*

At the global level, cooperation and coordination is essential. As Prah Ruger notes, “[m]ost observers agree that improving global health in the twenty-first century will require coordination and cooperation among states, using both legal and non-legal mechanisms.”<sup>90</sup> Global health justice also requires coordination with various international institutions and non-state actors. It makes sense that Prah Ruger labels her aspirational model as one of *shared* health governance:

No one (or set of) institution(s) or actor(s) on its own is able to perform [the] core functions and meet [the] fundamental needs [of global health justice]. As such, [shared health governance] parcels out respective roles and responsibilities at the global, state, local, and individual levels based on functional requirements and needs, identifying actors and institutions, their obligations, and how they are held accountable.

In short, global health governance is a team sport. One might even say that it takes a village to govern the global village.

The same applies with domestic regulatory governance. No regulatory organization on its own can gather all needed information, observe all possible regulated conduct, or change everyone’s behavior.<sup>91</sup> To activate the behavioral change needed to solve problems, domestic regulatory bodies often work best if they fulfill a role akin to the conductor of an orchestra—that is, by directing and steering others and leveraging businesses’ own capacities to fulfill regulatory functions.<sup>92</sup>

In the end, “[a] regulator’s performance depends on other institutions and entities in the overarching nexus of relationships within which it is embedded.”<sup>93</sup> The initial creation of a regulatory organization necessarily depends on others—e.g., members of a legislature—who give the regulatory body its authority, define its mandate and its legal constraints, and determine its funding and staffing levels. The regulatory organization is also embedded in a larger governmental system comprising other administrative agencies and bodies at different levels of government that interact with and affect the regulatory organization’s ability to carry out its mandate. The degree of public trust and legitimacy that the regulator enjoys will also be partly affected by the overall political environment within which it is situated. Because “[t]he regulator is just part of an overall ‘system’ that includes both other governmental entities as well as the industry that it regulates,” it must learn to act strategically and in coordination with these various other moving parts of the governance system.<sup>94</sup>

### 6. *Draw on a rigorous base of evidence and analysis.*

A domestic regulator, as with any institution involved in global health governance, can only expect to make sound decisions when its leaders are informed by the best available evidence and by carefully considered analysis. This is an obvious but too often neglected lesson that bears repeating.

This lesson follows directly from Prah Ruger’s emphasis on the significant role for “empirical evidence of effectiveness, efficiency, and accountability” in global health governance.<sup>95</sup> She favors reliance on “evidence-based standards and best practices” for

public health interventions,<sup>96</sup> and warns appropriately that “[u]nintended consequences are always a danger.”<sup>97</sup> She proposes a “Global Institute of Health and Medicine” that “would provide the needed scientific knowledge to craft effective policies and inform both domestic and global systems.”<sup>98</sup>

In much the same way, domestic regulatory decision-makers must seek out the best available scientific and economic analysis to inform policy and management decision-making. Yet the systematic development of regulatory analysis remains of relatively recent vintage and to date has been limited to mainly the prospective analysis of new regulations—so-called “RIA” or “regulatory impact assessment.”<sup>99</sup> Although RIA practices can now be found in all the major economies, the same cannot be said of retrospective evaluation of regulations once adopted.<sup>100</sup> Furthermore, numerous opportunities remain for regulators to strengthen their use of data analytics in enforcement and oversight management.<sup>101</sup>

With the rise of populism around the world, certain countries are showing signs of devaluing expertise.<sup>102</sup> At various points during the COVID-19 crisis, for example, the heads of state in the United States and Brazil openly flouted recommendations from scientists.<sup>103</sup> U.S. President Donald Trump even endorsed the use of unproven and potentially dangerous medications, and he planted seeds of doubt about public health data on CoV-2 cases and fatalities.<sup>104</sup> Not only do such actions undermine public trust and legitimacy, they may also encourage risky behavior that only exacerbates a public health crisis. Needless to say, domestic governance still can benefit from greater reliance on empirical evidence and analysis.

#### 7. *Treat regulation as a relational activity rather than a mechanistic structure.*

As vital as it is for regulatory decisions to be informed by evidence and analysis, it is also important not to mistake regulation for little more than a challenging mathematical or engineering problem that can be solved by finding the right answer. As many of the preceding lessons already suggest, domestic regulation—as with governance more generally—is a *relational activity*. It is, at its best, very much “shared” governance in the fullest sense of that term: interactive and iterative, and intersecting with many different actors and sectors. Partly that is because the world is changing, with new regulated entities and restructured existing ones appearing constantly. But mainly regulation is relational because it is ultimately about human behavior and how to shape, direct, and modify that behavior. To regulate well requires actions taken by people in *regulatory* organizations to influence actions taken by people in *regulated* organizations, in the face of incentives and constraints created by other people in still other organizations. Regulation, in other words, is sociological.

Regulation’s sociological or relational character begins with its very origins. The process of initially authorizing regulation of a sector or an activity usually gives regulation the kind of public backing that Prah Ruger argues is needed to make progress toward global health justice.<sup>105</sup> The public backing which leads legislatures to pass regulation-authorizing legislation stems often from either broad social movements or from crises or catastrophes that make the need for regulation more evident to the broader public.<sup>106</sup> Regardless of new legislation’s precise path, the early years of any new regulatory regime tend to enjoy some political and social tailwinds behind it. Those tailwinds, and any new

social norms they engender, help reinforce the same behavioral changes that any new set of regulations will aim to foster.

Regulation does not operate in a social vacuum. It is situated in a social and political context that affects its performance and meaning. This is so despite the fact that many regulators and scholars still seem to treat the most important regulatory questions as being ones of how the rulebook should be written. These drafting and design questions are certainly not unimportant, and I would not suggest for a moment that they should be answered based on hunches instead of sound analysis. But getting the rule's design "right" is only part of the activity of regulating. The rules on the books are only part of the story.

Regulation is not a machine, but instead is an ongoing, and often conflict-ridden, set of relationships between people in and out of government. Recognizing this reality both follows from and reinforces many of the preceding lessons—such as those about wielding hard power to reinforce soft power, remaining vigilant and dynamic, and coordinating with others. Most importantly, such recognition helps to explain why domestic regulatory governance and global health governance have so much in common: they are both about shaping human behavior in ways that will advance societal objectives.

## CONCLUSION

The relational and interactive nature of governance may be clearest on the global stage, where actors and institutions from many different cultures and legal systems must cooperate in a non-hierarchical social order. But that same relational, interactive character also describes governance at the domestic level. Global health governance and domestic regulatory governance share much in common, with some of the same general goals, strategies, and challenges. A realization of these commonalities should help facilitate greater cross-learning by scholars and practitioners who too often work within relatively limited domains. It is for this reason that an attentive reading of Jennifer Prah Ruger's recent book, *Global Health Justice and Governance*, can repay students of domestic regulation, offering a set of important lessons about how to approach the task of regulating well.

The Great Pandemic that emerged in 2020 has laid bare a number of harsh realities about inequities of health conditions and economic security around the world, revealing how much work remains to be done to deliver justice for all of humanity. The pandemic has also demonstrated the crucial role for high-quality domestic governance in successfully preventing and responding to global health problems.<sup>107</sup> The pursuit of excellence in domestic regulation will thus be integral to efforts to secure improved health conditions throughout the world. In that pursuit, regulators, policymakers, and members of the public will do well to keep in mind that regulation is not a self-implementing machine that operates separate from society. Regulation does not run on autopilot. Instead, it demands ongoing vigilance, adaptability, and responsiveness to changing circumstances and new risks. It requires adequate leadership, expertise, and resources to engage on an ongoing basis with a host of governmental and nongovernmental actors—not merely to deploy and enforce binding rules, but also to leverage social norms and other private pressures for behavioral change. Prah Ruger's model of shared health governance at the global level offers its readers an important vision for how regulators can best help make the world a better and healthier place.

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- <sup>56</sup> Ruger rightly recognizes the necessary interdependence between global and domestic governance. Ruger, 232. The final chapter of her book offers guidance specifically on domestic governance and merits a particularly close reading by anyone interested in national or subnational public health policy. Ruger, 359–381.
- <sup>57</sup> Prah Ruger, 83.
- <sup>58</sup> Prah Ruger, 339.
- <sup>59</sup> Prah Ruger, 340.
- <sup>60</sup> Prah Ruger, 339.
- <sup>61</sup> This goal has been institutionalized in regulatory practices and procedures. For example, in the United States, Executive Order 12,866, which has governed federal regulatory decision-making for more than a quarter century, specifically calls for regulators to seek to ensure that the expected benefits of new regulations will “justify” their expected costs. An earlier, even stronger, manifestation of the same tendency to focus on aggregate effects had been reflected in Executive Order 12,866’s predecessor, Executive Order 12,291, which called for benefits to “outweigh” costs.
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- <sup>76</sup> Prah Ruger’s treatment of the World Health Organization’s (WHO) struggles to maintain legitimacy as well as efficacy illustrates well the intertwined connections between substantive outcomes and procedural fairness. Ruger, 247–265.
- <sup>77</sup> Prah Ruger, 180. Ruger also sees an important role for global and domestic institutions to foster “public will” in support for health justice, a role that will undoubtedly be aided by institutional trust and legitimacy. Ruger, 290–291.
- <sup>78</sup> Cary Coglianese, *Listening, Learning and Leading: A Framework for Regulatory Excellence* (Philadelphia: Kleinman Center for Energy Policy, 2015), 75–76, [https://kleinmanenergy.upenn.edu/sites/default/files/spotlightonresearch/Listening%2C%20Learning%2C%20Leading\\_Coglianese.pdf](https://kleinmanenergy.upenn.edu/sites/default/files/spotlightonresearch/Listening%2C%20Learning%2C%20Leading_Coglianese.pdf).
- <sup>79</sup> Daniel Carpenter, *Reputation and Power: Organizational Image and Pharmaceutical Regulation at the FDA* (Princeton: Princeton University Press, 2010).
- <sup>80</sup> Maria De Benedetto, “Regulating in Times of Tragic Choices,” *The Regulatory Review*, May 6, 2020, <https://www.theregreview.org/2020/05/06/de-benedetto-regulating-times-tragic-choices/>.
- <sup>81</sup> David Vogel, “The Role of Policy Learning and Reputation in Regulatory Excellence,” in *Achieving Regulatory Excellence*, ed. Cary Coglianese (Washington, D.C.: Brookings Institution Press, 2017), 207, 221–222.
- <sup>82</sup> Prah Ruger, 241.
- <sup>83</sup> Prah Ruger, 185.
- <sup>84</sup> Prah Ruger, 201.
- <sup>85</sup> Prah Ruger, 239.
- <sup>86</sup> Prah Ruger, 185.
- <sup>87</sup> Cary Coglianese, “Obligation Alleviation During the COVID-19 Crisis,” *The Regulatory Review*, April 20, 2020, <https://www.theregreview.org/2020/04/20/coglianese-obligation-alleviation-during-covid-19-crisis/>.
- <sup>88</sup> Cary Coglianese and Jennifer Nash, “The Law of the Test: Performance-Based Regulation and Diesel Emissions Control,” *Yale Journal on Regulation* 34, no. 1 (2017): 33–90, [https://scholarship.law.upenn.edu/cgi/viewcontent.cgi?article=2714&context=faculty\\_scholarship](https://scholarship.law.upenn.edu/cgi/viewcontent.cgi?article=2714&context=faculty_scholarship).
- <sup>89</sup> Cary Coglianese, “Regulatory Vigilance in a Changing World,” *The Regulatory Review*, February 25, 2019, <https://www.theregreview.org/2019/02/25/coglianese-innovation-regulatory-vigilance/>; Cary Coglianese, “Regulatory Abdication in Practice,” *University of Pennsylvania Institute for Law and Economics, Research Paper Series*, no. 20-11 (February 2020), <https://dx.doi.org/10.2139/ssrn.3535895>.
- <sup>90</sup> Prah Ruger, 261.
- <sup>91</sup> Cary Coglianese, Richard Zeckhauser, and Edward A. Parson, “Seeking Truth for Power: Informational Strategy and Regulatory Policy Making,” *Minnesota Law Review* 89 (2004): 277–341.
- <sup>92</sup> Sometimes this role for a regulator is described as one of being a “meta-regulator.” Christine Parker, *The Open Corporation: Effective Self-regulation and Democracy* (Cambridge: Cambridge University Press, 2002).
- <sup>93</sup> Coglianese, *Listening, Learning, and Leading*, 14.
- <sup>94</sup> Coglianese, *Listening, Learning, and Leading*, 14.
- <sup>95</sup> Prah Ruger, 184.
- <sup>96</sup> Prah Ruger, 200–201.
- <sup>97</sup> Prah Ruger, 243.
- <sup>98</sup> Prah Ruger, 243.
- <sup>99</sup> Claudio M. Radaelli, “Regulating Rule-Making via Impact Assessment,” *Governance* 23, no. 1 (January 2010): 89–108, <https://doi.org/10.1111/j.1468-0491.2009.01468.x>; Jonathan B. Weiner, “The Diffusion of Regulatory Oversight,” in *The Globalization of Cost-Benefit Analysis in Environmental Policy*, eds. Michael A. Livermore and Richard L. Revesz (New York: Oxford University Press, 2013); Organization for Economic Co-operation and Development, *OECD Regulatory Policy Outlook 2018* (Paris: OECD Publishing, 2018).
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<sup>107</sup> Cary Coglianese and Neysun A. Mahboubi, “Administrative Law in a Time of Crisis: Comparing National Responses to COVID-19,” *Administrative Law Review* 73 (2021): 1-18.