Chapter 16

A Systems Approach to Regulatory Excellence

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Systems are all around us. They make up the technology that we use in our daily lives: computers, cars, and cell phones, to name just a few. Not only are common technological devices themselves complex systems of interactive components such as gears, wiring, chips, software, and the like, but the devices interact within larger systems too: computers interact with the Internet; cars operate within a larger transportation system; cell phones tap into telecommunications systems; and so forth. Furthermore, the processes by which manufacturers produce technological devices and build the larger systems in which they operate depend vitally on a variety of systems, such as supply-chains and other industrial systems. The uses to which modern technologies are put also become embedded in complex systems, something particularly evident for computer systems which are used in everything from running hospitals to managing the electrical grid. But systems are much more than technology; they involve people interacting with each other, in teams, offices, firms, and sectors, and then interacting with technology and with the environment within which they are situated. Systems even comprise other systems interacting and overlapping with each other.

A system can be formally defined as "a set of elements or parts that is coherently organized and interconnected in a pattern or structure that produces a characteristic set of behaviors, often classified as its 'function' or 'purpose.'"[1] How any system functions can only truly be known by observing its behavior or performance. Moreover, no single element or actor is in control of a system's performance; that is, it is possible for the function or purpose of the system to be at odds with the intentions of some or even all of the actors in that system. Systems do not always act in a linear fashion; often multiple factors interact with each other to produce results that can be hard to foresee. Actions taken at one part of a system can form feedback loops that affect other parts of the system. We inhabit a complex world today, and that complexity arises because of the many systems in which we are situated or with which we interact. These systems often help make the world a better place, but they also can sometimes create serious problems, such as in terms of safety, reliability, sustainability, or other important values. As a result, systems need to be managed and regulated so as to promote positive outcomes and minimize negative ones. Yet systems create particular challenges for regulators because the different actors and components within them are interacting in hard-to-discern ways. The different actors within any system are often seeking to achieve different goals simultaneously, and these goals that can be at odds with the regulator's mission. Seldom will there exist any single, clear point of regulatory "control" that can determine the results of a system.

Excellent regulators understand these challenges and overcome them to achieve regulatory goals. Whether in the fields of environmental protection, occupational health and safety, transportation safety, or health care delivery – among many others – the very best regulators will take a systems approach to their work. By a systems approach, I mean one that defines the regulatory problem as one of influencing the order that emerges in systems, often trying from the bottom-up to guide those systems to move towards socially useful and productive goals. The best way regulators can influence the emergence of order in systems is to enable actors in those systems to find ways to integrate those socially useful and productive goals into their everyday processes and activities. In this way, excellent regulators work to ensure that each of the elements of a system works synchronously in pursuit of both private and public goals simultaneously. The best regulatory leaders learn that, to succeed in influencing any complex system to promote public value, they must abandon the quest for a single, fixed point of control – such as by crafting the one, "best" rule. Instead, they must learn that regulatory excellence has more to do with "strategically, profoundly, madly, letting go and dancing with the system."[2]

Why a Systems Approach is Vital for Achieving Regulatory Excellence

When regulators consider the patterns of interactions occurring within system – whether across people, firms, technologies, the environment – it creates better opportunities to identify problems, understand what causes them, and imagine new ways to solve them by influencing interactions so the system can be set on a path for simultaneously achieving productive goals and public policy goals.[3]

In the United States, the publication in 2000 of a now well-known Institute of Medicine report, *To Err is Human: Building a Safer Health System,* brought to public attention the occurrence of as many as 98,000 deaths caused by health care errors.[4] This report is also significant because it shifted attention away from a conception of risk that treated errors as caused by negligence on the part of individual health professionals to a conception that considered harm to be a product of "preventable" system errors.[5] The report's authors relied on James Reason's distinction between "active errors" and "latent conditions" – or system errors[6] In this frame of analysis, an "active error" is the act or decision that contributes to harm, while a latent or system error increases the risk that operators will make such errors.[7] For example, although it is well-known that the drug vincristine used in chemotherapy should be injected into patients only intravenously, a pattern of reported incidents has arisen across many different health care institutions in which doctors have mistakenly injected the drug into the spinal cavity of patients, causing their patients to die. Although in such cases it is true that active errors occurred that caused the death of patients, these incidents also occurred because of system errors in the organization of hospitals that created the conditions for the incorrect delivery of vincristine.[8] Examples of such system errors include modifications to medicine protocols, improper labeling and packaging of vincristine, and other communications errors.[9]

The distinction between active failures and latent or system errors gave rise to Reason's "Swiss cheese model of accident causation."[10] In this model, which is typically visualized by lining up several slices of different hunks of Swiss cheese, with the holes in the cheese representing gaps in the defenses protecting operators and patients from harm. An accident or active error results when the gaps in the defenses – the holes in the Swiss cheese – line up. This way of thinking about accidents has proven highly influential for regulators working in a variety of contexts in which they operate under a public mandate to reduce accident risks, including aviation safety and workplace safety in addition to the regulation and management of health care delivery. A systems approach to assessing regulatory problems is, in most settings, essential for adopting a "risk-based" approach to regulation.[11]

Recognizing that problems as varied as medical errors and offshore oil spills arise not just from negligent individual behavior but also from larger system failures can lead to the new types of solutions. Mandating checklists, for example, may prove highly effective for safely managing complex medical procedures, even though such measures might not at first glance have been thought necessary for truly competent individual practitioners.[12] In a similar vein, recognition of the system-like qualities of hazardous waste management has led U.S. environmental regulation to mandate that written documentation accompany every drum of hazardous waste from its point of generation, through transporting, through disposal, with information filled out at each step and a copy of the completed documentation returned to the generator once the waste has been disposed.[13]

Identifying problems as system breakdowns – or unintended alignments in the gaps in a system's defenses – does not mean that all problems can readily be solved.[14] Merely naming a pattern of interactions between actors as a "system" is not always enough to identify discrete leverage points that regulators can use to influence those interactions. In a number of domains, regulators fully recognize the systematic nature of the underlying problems but also recognize that they, as regulators, lack the real-time, fine-grained information needed to know what interventions might be best. In realms as varied as environmental protection, occupational health and safety, food and drug regulation, and pipeline safety, regulators have made use of an regulatory strategy known as management based regulation, through which regulators try to engage firms' managers in the analysis and management of their own systems with the attainment of regulatory goals in mind.[15] Although the precise requirements of any management-based regulation varies, it generally requires firms' managers to engage in a planning process through which they identify sources of potential problems, develop practices and procedures to solve them, and document their implementation of the plan and procedures. This form of regulation seeks to "'build in' regulatory considerations at every stage of the production process, to improve social performance."[16] By requiring that managers consciously plan to reduce social harm, management based regulation seeks to influence the interactions between managers and workers in ways that will change the outcomes of the system.

Why Systems Are Difficult to Regulate

Management-based regulation is premised on a belief that managers using bureaucratic planning can find ways to control the systems which they oversee.[17] Usually this planning takes a reductive analytical form that tries to break a problem into its component parts and then attack each part separately. In food processing, for example, a process known as hazard analysis and critical control points (HACCP) planning calls on managers to identify discrete intervention points where cleaning should take place, temperatures should be controlled, or other concrete steps should be taken.[18] Nancy Leveson refers to an approach like this as a "divide and conquer" approach to problem solving:

> In the traditional scientific method, sometimes referred to as *divide and conquer*, systems are broken into distinct parts so that the parts can be examined separately: physical aspects are decomposed into separate physical components while behavior is decomposed into events over time. Such decomposition (formally called *analytic reduction*) assumes that such separation is feasible: that is, each component or subsystem operates independently and analysis results are not distorted when these components are considered separately.[19]

Unfortunately, especially with complex, fast-changing systems, management-based regulation may not work very effectively, especially if it calls for long cycles of planning and approval rather than near-constant cycles of monitoring and adaptation. A "divide and conquer" approach may not always be enough to influence interactions in systems to produce socially desirable outcomes – and producing socially desirable outcomes is what an excellent regulator strives to accomplish.

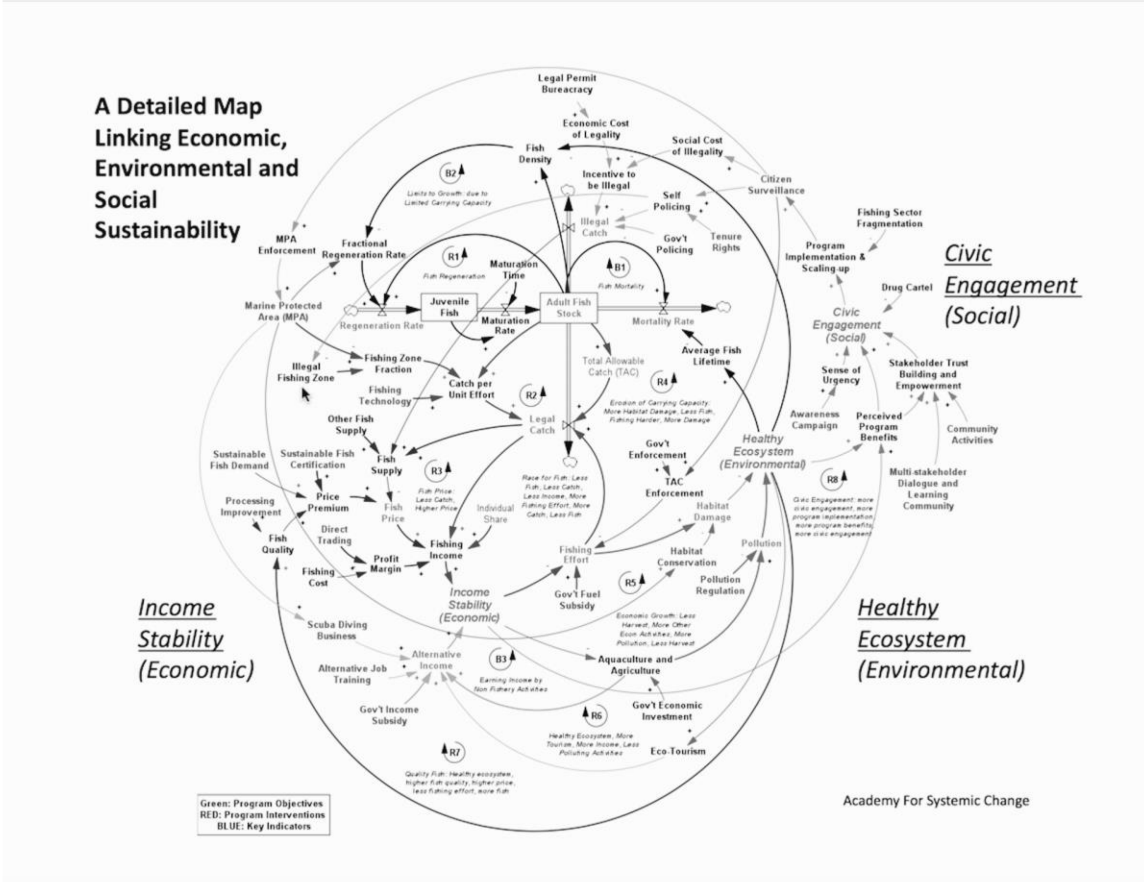
Influencing others so as to enable them to move a system towards multiple goals simultaneously – one goal being the regulator's – can be difficult because of at least five core characteristics of systems that regulators face. Many of these systems can be complex, dynamic, tightly linked, ordered both from the top as well as from the bottom, and uncertain in their boundaries and inner workings. These same characteristics that make regulating systems challenging also make it possible for excellent regulators to imagine new ways to achieve their goals..[20]

1. Systems are complex

The connections between patterns of interactions between actors in a system and the outcomes produced by that system are predictable but are not predictably regular. Systems cannot be fully described and mapped but neither do they produce random outcomes.[21] Systems exhibit non-linear responses to change. This means that systems can be at once resistant to change and simultaneously be hypersensitive to change when a system reaches a tipping point.

Figure 1 provides a partial representation of the complex system surrounding the regulatory challenge of ensuring the viability of fisheries.[22] It depicts the complex relationships between ocean ecosystems, commercial fishers, aquaculture and agriculture activities, government actors, and those who live near and make use the ocean for recreation. This model shows the multiple pathways and feedback loops by which these various actors are connected in the system. At the center of the model are stocks of fish —the key outcome of concern that the model shows is affected by the dynamic interactions between the various system components. Appreciating the complexity of the system can provide useful insights to fisheries regulators. At first glance, a regulation imposing a total quota on allowable fish catch might seem to be an effective way to restore fish stocks. But even if regulators could successfully enforce such limits (something that may be difficult) this intervention could nevertheless have unintended consequences. It could reduce the incomes of fishers, leading them to pursue alternative forms of livelihood in agriculture and aquaculture, which in turn could be more damaging to the ecosystem and cause further erosion of fish stocks.[23] An fuller appreciation of the complexity of the system would open up the possibility of alternative governmental strategies, such as the promotion of civic engagement that might foster social norms promoting behavior that better maintains healthy fish ecosystems.[24]

Figure 1: The Complexity of Fisheries Systems



2. *Systems are dynamic*

Many systems are constantly changing, and the distance between their current state and regulatory goals is often in constant flux. Safety outcomes, for example, can be considered "dynamic non-events" to indicate that the non-occurrence of accidents is supported by many changing interactions between actors, groups and organizations in a system. [25] Regulators are unable to influence systems very well if they overlook the dynamic properties of systems, and yet this is a tendency that too many regulators succumb to, even if unintentionally. They put a rule in place to address a problem and then move on to something else. In this way, they may succeed in solving "yesterday's problem" but fail to keep pace with technological, economic, social, or environmental changes.[26] Even when organizations and systems seem to be working well with respect to regulatory goals, their performance may degrade over time. This can be the result of organizational processes that allow for the "normalization of deviance"[27] or that persistently "sacrifice" regulator goals in favor of pressing production goals.[28]

3. *Systems are tightly linked*

Sometimes it may appear as if adding a public policy goal to an existing system is a simple arithmetic process, adding just an extra layer of planning to the existing management structures and planning processes. Yet in complex systems, the tight linkages between actors can create unpredictable sequences of events and accidents that are difficult for regulators and managers to prevent.[29] Adding a regulatory intervention may generate a non-linear result because it requires that patterns of interactions between actors change as those actors learn how to integrate the new public policy goal so that the system can simultaneously meet productive and safety goals. The nature and extent of the change required of actors is one reason why many actors in systems adopt a ritualistic response to regulation designed to achieve a public policy goal. In Neil Gunningham and Duncan Sinclair's study of mine safety regulation, the mines with poor safety performance exhibited a lack of trust between management and workers, producing a ritualistic response to a required management system. By contrast in the high ranking mines, workers and managers used the management system as an opportunity to improve both productive and safety goals.[30] Regulators should expect these kinds of interactive linkages and seek to ensure that actors in systems have spaces and time in which they are able to experiment with new patterns of interactions to achieve new regulatory goals.[31]

4. Systems can emphasize emergence of order from the bottom-up

In many complex systems, interactions between agents "lead to dynamic patterns created by iterative and mutual adaptation."[32] Order emerges out of these interactions between agents.[33] This property of emergence allows individual-level adaptation between agents to give rise to new or changing states of order at the macro or system level.[34] For regulators, the emergence of order from interactions between actors or elements may be perhaps the single most important characteristic of a system.[35]

Outcomes, such as safety, often emerge "bottom-up" from a variety of interactions. At least, the degree to which different organizations or parts of systems are affected by bottom-up emergence versus top-down imposition can lead to different outcomes. Responses to the safety management systems in Gunningham and Sinclair's study varied across mine sites. In the low ranked mines, there was a culture of mistrust that arose out of "a long history of antagonism between management and unions."[36] By contrast, in high ranked mines, "worker input and engagement (in short, ownership) was actively sought in the implementation of new safety systems and initiatives."[37] Excellent regulators will be attentive to these differences and will engage with the process of emergence in order to shape the direction that the system takes.

5. *Systems are difficult to see*

"Systems" do not follow organizational charts or institutional patterns. The complexity, dynamism, interactivity, and bottom-up quality of many systems inherently makes them difficult to understand and map. Even the same organization can have different systems or sub-systems within it, and yet while not visible to the outside regulator they could prove critical to overall system performance. This presents a major challenge for regulators. Excellent regulators will recognize the challenge and seek to gather the information needed to understand the system they seek to influence.[38] They will seek to engage with actors in the systems in order both to learn about the system as well as to influence interactions between actors in those systems. Ultimately, changes in the outcomes of these interactions will prove more visible than the system itself; however, the excellent regulator is strategic and not just lucky, and therefore needs to peer into the system so as to be able to connect the dots between the regulator's interventions and the outcomes that emerge.

Excellent Regulators *Can* Influence Systems

Despite the difficulties, regulators can, and sometimes do, succeed at influencing systems in ways that deliver public value.[39] An instructive example would be the U.S. Food and Drug Administration's experience in asserting regulatory authority over tobacco during the latter half of the 1990s. As FDA commissioner at that time, David Kessler took the initiative to assert FDA authority tobacco for the first time, reversing a longstanding position the agency itself had taken declaiming the authority to regulate tobacco products. By 1995, when President William Clinton announced that the FDA would formally propose a rule "to protect the young people of the United States from the awful dangers of tobacco,"[40] Kessler had succeeded in moving forward with a regulatory "initiative that most people outside the FDA would have thought unimaginable only a few months before."[41] The agency's proposal had sparked a political firestorm, with the tobacco industry mounting a major lobbying campaign against the agency and members of Congress from tobacco-producing districts berating Kessler and challenging him vociferously at legislative hearings. Nevertheless, Kessler moved the regulation forward and in 1996 the agency made final its regulation limiting young people's access to cigarettes and restricting tobacco companies' ability to market their products to children,[42] an historic regulatory step that prompted both the President and Vice-President to praise the rule at a special press conference held the White House Rose Garden.[43]

The FDA's regulatory saga turned out not to be entirely rosy. The tobacco industry, not surprisingly, challenged the rule in court, and several years later the U.S. Supreme Court declared the rule to be invalid, concluding that the FDA lacked statutory authority to regulate tobacco products. [44] Yet while that litigation was still pending, the larger political and legal system showed signs of shifting, no doubt in part due to the FDA's actions. In late 1998, tobacco companies reached a settlement with state governments over claims that cigarettes had increasing public health spending, a settlement that amounted not only to payments of more than $200 billion over a 25-year period but also acceptance of some of the very restrictions included in the FDA's rule.[45] While the FDA's rule was ultimately found to be unlawful, it did help change the state of the larger system of smoking and the sale and marketing of tobacco products.[46] Steve Parrish, a Vice President of Philip Morris, reportedly told David Kessler that for tobacco corporations "it was no longer a question of winning lawsuits," it was rather "a question of obtaining permission from society to continue to exist."[47] By 2009, Congress did what had been completely unimaginable a little more than a decade earlier: it gave the FDA the express authority to regulate tobacco that the Supreme Court had held the agency lacked.[48] The congressional findings in the Family Smoking Prevention and Tobacco Control Act mirrored the findings that Commissioner Kessler and his team had made when issuing the FDA's original tobacco regulation. Under the authority of the new statute, the FDA re-issued in 2010 the earlier restrictions that Kessler had pushed forward in the face of opposition.[49]

To initiate the FDA's original rulemaking in the late 1990s, Kessler navigated and bumped up against several important systems, economic, political, and legal, among others. But he also used systems thinking in the substantive policy approach his agency took to addressing the public health threat created by smoking. He was, in the end, normatively closed to the growing, manufacturing, marketing, and use of tobacco but along the way he was cognitively open to and aware of the social as well as medical aspects of the systems that created addiction to smoking and contributed to more than 400,000 premature fatalities per year in the United States.[50] David Kessler and many of those who worked him in the FDA were relentlessly focused on the goal of improving public health, but disciplined in how he and his team approached the practical but vital problem of learning what they needed to know to regulate the systems involved in growing, manufacturing, marketing and consuming tobacco products.[51] Their disposition of openness enabled the FDA to learn about the "linkages, relationships, interactions, and behaviors"[52] that made up the system for growing, manufacturing, marketing and consuming tobacco. In turn this enabled the FDA to find a leverage point to influence this system by focusing in the marketing and consumption of tobacco by young people.[53] They realized that a key leverage point in solving the public health problem created by the larger tobacco market system was at the point of entry into the market. Keeping children and teens from starting to smoke could help break a cycle of addiction and, with time, slow the rate of smoking and smoking-related diseases.

In relentlessly pursuing the goal of improving public health by influencing the consumption of tobacco, Kessler made use of the fundamental characteristics of systems. He did not just search for a the regulator's instinctive tool to reduce a harm: a ban on the harmful activity.[54] Rather, Kessler and his team set out to learn about linkages and relationships between actors in this system and ultimately settled on a regulatory strategy that was an effective leverage point in setting in motion the process of changing patterns of consumption of tobacco by consumers. The use of this leverage point – namely, by limiting the sale of tobacco to young people – also conformed to the structure of the legal system that recognized special responsibilities for the protection of children. This strategy took advantage of the tight linkages between actors in systems. It recognized that *any* change in the system for marketing and consuming tobacco would change the interactions between *all* the actors in the system. It also took advantage of the property of emergence as young people and their families responded to the regulation. It relied upon this new emergent order being one that would put the system for growing, manufacturing, marketing and consuming tobacco on the defensive, even should the FDA lose its initial battle in the courts over its regulation. By taking bold action, and winning the visible support of the President of the United States for the FDA's initiative, Kessler influenced more than just what the rule immediately affected – product marketing aimed at children – but it put the entire country, through its cultural, social, and even legal systems, on a path that would eventually yield significant positive outcomes for public health.[55]

Advice for Regulators Seeking to Influence System

What are the lessons for regulatory leaders who seek excellence in their work? Excellent regulators must be committed, smart, nimble, vigilant, well-resourced, trusted, and ultimately ever-cognizant of the important role that systems play in causing regulatory problems and in solving them.

Be committed. Excellent regulators make it known to the industries and actors they seek to influence that they are singularly motivated by public policy goals.[56] By both word and deed, excellent regulators communicate a relentless will to achieve public policy goals. This does not mean pursuing those goals at any cost, or in ways that conflict with the interests, values, and commitments of the legal and political institutions that empower the regulator to act. But it does mean the regulator is clear about its public-interested mission. All those actors and organizations who are in the regulator's domain need to know that the regulator will amass knowledge with the aim of finding leverage points to achieve its stated policy goals.[57]

Understand to changing economic, social, technological, and political conditions. An excellent regulator is smart. But this is not a general invocation to learn for the sake of learning. Rather it is an invocation to learn about the "linkages, relationships, interactions, and behaviors" in a system with the aim of finding effective leverage points to influence those systems. Learning about a system affecting the regulator's goals may seem to be impossibly difficult, but it is the only way a regulator can act strategically and effectively to influence a system.

Remain nimble. It is not enough for a regulator to learn how a system worked in the past or even how it works today. Adapting to change may be difficult for any organization – especially legal ones – but the complex, dynamic nature of systems means that they will be in constant flux, changing as new actors enter the system or background conditions change. Fortunately, this should mean that there will (nearly) always be leverage points that excellent regulators can use to influence systems – but only if they find them.

Stay Vigilant. Excellent regulators do not assume that just because they adopt a regulation, the regulatory problem will be solved. Initial implementation of a regulation is just the start of learning how to change the dynamics of systems. Excellent regulators will be mindful of the potential for tight linkages in systems and of the emergence of bottom-up order to create unintended consequences as systems adapt to the implementation of the regulation. Regulators should also be vigilant in measuring changes in outcomes of systems as those systems respond to the implementation of the regulation.

Build capacity. Excellent regulators build the capacity to influence the interactions between actors in systems to achieve public policy goals. The dynamic nature of systems means that capacity needed to influence interactions between actors in systems will change over time. Excellent regulators build capacity so that they are able to respond flexibly to new challenges as they arise. As David Levi-Faur argued in Chapter 14, this may mean building capacity by including different forms of experts, for example, historians, criminologists, and political scientists.[58] It decidedly means that they need the adequate funding that Shelley Metzenbaum and Gaurav Vashisht call for in Chapter 10.[59] The FDA's experience with tobacco revealed the importance of building the in-house to investigate an industry and understand how it operates.

Maintain public trust. Excellent regulators generate the support needed to build the capacity they need to fulfill their mission. They are able to do this because they are entrusted to use this capacity wisely and in ways that conform to the values and commitments of the legal and political institutions that authorize and support them. They are entrusted in this manner because they stay vigilant and are committed to the task of achieving socially beneficial outcomes. David Vogel's account of the California Air Resources Board in Chapter 13 serves to illustrate how valuable it can be to a regulator to build and maintain a reputation for excellence.[60]

Remain systems-minded. Above all, excellent regulators must remain "systems minded." They must find leverage points that simultaneously influence systems *and* conform to the interests, values, and commitments of the legal and political systems in which they operate. Conforming to these interests, values, and commitments increases the likelihood of the success of a particular regulatory initiative. But it also gives rise to a relationship of trust with the political bodies that authorize and fund regulators to pursue the achievement of public policy goals. Ultimately excellent regulators work synchronously with the systems that they are seeking to influence and with the political and legal systems that support them as they pursue public policy goals. It is this working synchronously with systems and their various components that entails the essential ability of an excellent regulator "to dance with systems.[61]

Conclusion

Given the inherent difficulties involved in regulating complex systems, an excellent regulator will never be a perfect regulator. It will, though, consistently seek and make use of leverage points in systems. These leverage points must simultaneously put regulated systems on a path toward achieving public policy goals as well as conform to the interests, values, and commitment of legal, economic, and political institutions that support the regulator. The leaders of regulatory organizations who seek excellence must always seek to understand the bigger – and fully complex and dynamic – picture of what causes the problems they are tasked to solve, so they can then identify strategies to change the dynamics of the relevant systems and put them on a path toward achieving regulatory policy goals.

Notes

[1] Donella Meadows, *Thinking in Systems: A Primer*, (White River Junction, Vermont: Chelsea Green Publishing, 2008), p.188.

[2] Ibid., at 165.

[3]Ruthanne Huising & Susan Silbey, "Governing the gap: Forging safe science through relational regulation," *Regulation & Governance,* vol. 5 (2011), p.36 ("Relational regulation is a form of sociological citizenship.").

[4] Institute of Medicine, *To Err is Human: Building a Safer Health System* (Washington: National Academies Press, 2000). See also Robert Wachter, *Internal Bleeding: The Truth Behind America's Terrifying Epidemic of Medical Mistakes*, (New York City, New York: Rugged Land, 2004), at pp.55-64.

[5] Institute of Medicine, op. cit., pp.1-5.

[6] James Reason, *Human Error* (Cambridge: Cambridge University Press, 1991).

[7] Institute of Medicine, op cit.., pp.65-66.

[8] James Reason, (2004). "Beyond the Organisational Accident: The Need for 'Error Wisdom' on the Frontline." *Quality & Safety in Health Care*, vol. 13 (Suppl II), pp. ii28-ii33.

[9] James Reason, *Organizational Accidents Revisited* (Boca Raton, FL: CRC Press, 2016).

[10] For a critical analysis of the "Swiss cheese model of accident causation," see Erik Hollnagel and others, "Revisiting the 'Swiss Cheese' Model of Accidents," (2006) EEC Note No. 13/06, May 10, 2016 (www.eurocontrol.int/revisiting-swiss-cheese-model-accidents).

[11] For a discussion of a risk-based approach to regulation, see Bridget M. Hutter, "A Risk Regulation Perspective on Regulatory Excellence," in Cary Coglianese, ed., *Achieving Regulatory Excellence* (Washington, D.C.: Brookings, 2016).

[12] Atul Gawande, *The Checklist Manifesto: How to Get Things Right* (New York: Metropolitan, 2011).

[13] U.S. Environmental Protection Agency, Hazardous Waste Manifest System, https://www.epa.gov/hwgenerators/hazardous-waste-manifest-system.

[14] Unfortunately, medical errors remain a much too-frequent cause of fatalities in the United States. Martin Makary and Michael Daniel, "Medical Error: The Third Leading Cause of Death in the US," *British Medical Journal*, vol. 353 (2016), p. 2135.

[15] Cary Coglianese and David Lazer, (2003). "Management-Based Regulation: Using Private Management to Achieve Public Goals," *Law and Society Review*, vol. 37 (2003), pp.696-700. Management-based regulation is so-named because it "self-consciously seeks to affect the way that businesses manage" their affairs." Cary Coglianese, "The Managerial Turn in Environmental Policy." *N.Y.U. Environmental Law* , vol. 17 (2008), p. 54. *See also* Cary Coglianese and Jennifer Nash, eds., *Leveraging the Private Sector: Management-Based Regulation for Improving Environmental Performance* (Washington, D.C.: Resources for the Future Press, 2006).

[16] Neil Gunningham and David Sinclair, (2009) "Organizational Trust and the Limits of Management-Based Regulation," vol.43 (2009), p.865, at pp.867-868.

[17] Coglianese, op. cit., p.70.

[18] *See* Coglianese and Lazer, op cit.; Peter J. May, "Social Regulation," in Lester M. Salamon, *The Tools of Government: A Guide to the New Governance* (Oxford: Oxford University Press, 2002).

[19] Nancy Leveson, *Engineering a Safer World: Systems Thinking Applied to Safety*, (Cambridge, MA: MIT Press, 2011), pp.61-62.

[20] Don de Savigny and Tahgreed Adam, *Systems Thinking for Health Systems Strengthening* (Alliance for Health Policy and Systems Research and World Health Organization, 2009), pp. 40-52.

[21] Leveson, *Engineering a Safer World*, op. cit., p.62.

[22] Joe Hsueh, "Fishery Causal Loop Diagram, Academy for Systemic Change" (Academy for Systemic Change, 2011 (www.academyforchange.org/wp-content/uploads/2012/08/Fishery-Causal-Loop-Diagram-2011.9.pdf).

[23] Ibid, at p.7.

[24] Ibid, at pp.8-12.

[25] James Reason, *Managing the Risks of Organizational Accidents*, (Aldershot, England: Ashgate Press, 1997), pp. 37, 107-124.

[26] On the pacing problem more generally, see Gary E. Marchant, Braden R. Allenby, & Joseph R. Herkert, eds., The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight (Heidelberg: Springer, 2011).

[27] Diane Vaughan, *The Challenger Launch Decision: Risky Technology, Culture, and Deviance at NASA* (Chicago: University of Chicago Press, 2009).

[28] David Woods, "Essential Characteristics of Resilience," in Erik Hollnagel, David Woods and Nancy Leveson, *Resilience Engineering: Concepts and Precepts*, (Aldershot, England: Ashgate**,** 2006), pp.21-33.

[29] Charles Perrow, *Normal Accidents: Living with High-Risk Technologies*, (Princeton, NJ: Princeton University Press, 1999). See also Woods, op. cit.

[30] Gunningham and Sinclair, op. cit., pp.890-891.

[31] See Katherine Kellogg, *Challenging Operations: Medical Reform and Resistance in Surgery*, (Chicago, University of Chicago Press, 2011), pp. 165-186 (importance of "relational spaces" to learn how to integrate new regulatory requirements). See also Ruthanne Huising and Susan Silbey, op. cit., pp. 33-37 (significance of macromanagement and "slack time" for compliance officers to engage in collaborative inquiry to support "relational regulation"), Steven Spear, "Fixing health care from the inside, today," *Harvard Business Review*, vol. 83 (2005), p. 89 (the importance of mastering the learning process rather than problem specific solutions).

[32] Volker Schneider, "Governance and Complexity," in David Levi-Faur, ed., *Oxford Handbook of Governance* (New York: Oxford University Press, 2012), p.137.

[33] Ibid., p.138.

[34] Ibid.

[35] Ibid., p.134.

[36] Gunningham, op. cit., p.16.

[37] Ibid., p.13.

[38] Cary Coglianese, Richard Zeckhauser, and Edward Parson, *Seeking Truth for Power: Informational Strategy and Regulatory Policymaking, Minnesota Law Review* vol. 89 (2004), pp. 277-341.

[39] On the concept of public value, see Mark H. Moore, *Recognizing Public Value* (Cambridge, MA: Harvard, 2013).

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[41] David Kessler, *A Question of Intent: A great American Battle with a Deadly Industry* (New York: Public Affairs, 2002), p. 333.

[42] Scott & Heymann, op cit., p. 19, 25.

[43] Ibid, p. 25.

[44] Kessler, *A Question of Intent*, p. 386.

[45] Ibid, p. 361.

[46] *FDA v. Brown & Williamson Tobacco Corp.*, 120 S. Ct. 1291 (2000).

[47] Kessler, *A Question of Intent*, p. 388.

[48] Family Smoking Prevention and Tobacco Control Act, Public Law 111-31 (2009).

[49] Food and Drug Administration, Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 75 Federal Register 13, 225 (Mar. 19, 2010).

[50] Gunther Teubner, "Introduction to Autopoietic Law," in Gunther Teubner (ed), *Autopoietic Law: A New Approach to Law and Society* (New York, NY: Walter de Gruyter, 1987), pp. 10-11. This systems perspective leads to a definition of regulation as one in which a regulator uses law "to trigger self-regulatory responses" in other systems. In order to be successful, a regulator must pursue a normative goal by making use of the properties of systems to explore ways of coordinating the interactions between legal, political and economic systems that are also cognitively open and normatively closed: Gunther Teubner, "Juridification – Concepts, Aspects, Limits, Solutions" in Gunther Teubner (ed), *Juridification of Social Spheres: A Comparative*

Analysis of in the Areas of Labor, Corporate, Antitrust and Social Welfare Law (New York, NY: Walter de Gruyter, 1987), pp. 19-22.

[51] Ibid, p. 260.

[52] Savigny & Adam, op. cit., p. 54.

[53] Kessler, *A Question of Intent*, chs. 35 & 36.

[54] T Katherine Kellogg, *Challenging Operations*, op. cit., pp.1-8. (The use of regulation to limit work hours was an "intervention" that was difficult to implement and it appears to have had little impact on improving patient safety).

[55] In this way, Kessler and the FDA accomplished what John Braithwaite describes as the "transformative" quality of regulatory excellence. John Braithwaite, "Responsive Excellence," in Cary Coglianese, ed., *Achieving Regulatory Excellence* (Washington, D.C.: Brookings, 2016).

[56] Richard Locke (2013). *The Promise and Limits of Private Power: Promoting Labor Standards in a Global Economy* (New York: Cambridge University Press, 2013), pp. 174-182.

[57] Ian Ayres and John. Braithwaite, *Responsive Regulation: Transcending the Deregulation Debate* (Oxford, England: Oxford University Press, 1992).

[58] David Levi-Faur, "Regulatory Excellence via Multiple Forms of Expertise," in Cary Coglianese, ed., *Achieving Regulatory Excellence* (Washington, D.C.: Brookings, 2016).

[59] Shelley H. Metzenbaum and Gaurav Vasisht, "What Makes a Regulator Excellent?: Mission, Funding, Information, and Judgment," in Cary Coglianese, ed., *Achieving Regulatory Excellence* (Washington, D.C.: Brookings, 2016).

[60] David Vogel, "Regulatory Excellence: The Role of Policy Learning and Reputation," in Cary Coglianese, ed., *Achieving Regulatory Excellence* (Washington, D.C.: Brookings, 2016).

[61] Meadows, op cit., p. 165.