Fundamentals of Regulatory Design

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DEDICATION

This book is for professional regulators, who strive to keep us all safe.

I hope in these pages to honor the importance of the role that regulatory practitioners play, and to recognize the complexity of the choices they face as they design their regulatory operations and carry out their public duties.

Regulatory practitioners inhabit the space between laws as enacted, and societal protections as delivered. What they choose to do, and how they choose to do it, matters a great deal and fundamentally affects the quality of life in a democracy.

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INTRODUCTION

This is my Coronavirus pandemic book. I imagine thousands of other books may have been written in roughly the same timeframe, a predictable consequence of academics, as non-essential workers, obliged to work from home for months on end.

For me, Friday March 13th 2020 was the last face-to-face teaching day at Harvard before the lock-down. This was the last day of my one-week executive program, “Strategic Management of Regulatory & Enforcement Agencies”, delivered for the 38th time at Harvard’s Kennedy School. The class, as usual, was made up of senior managers and executives from a broad range of regulatory, enforcement, and security agencies. They came from eleven different countries. Several of them faced two weeks mandatory quarantine once they got home, given evidence of rapidly growing infection rates in the United States. Friday 13th March 2020 was also the last face-to-face teaching day for Harvard University. The campus “de-densification” took immediate effect thereafter. Students were sent home for the remainder of the semester and online teaching through remote access very suddenly became the new normal.

My work for the first week at home was all about cancellations. Campus evacuations, lock-downs, travel restrictions, and ordinary prudence made it obvious that all the engagements with public agencies, teaching trips and courses that I had scheduled for the remainder of March through June 2020 had to be called off. That meant cancelling a total of 108 executive level classroom sessions,

90 minutes each, or 162 hours of face-to-face teaching time. These engagements included executive level courses of various lengths for mixed (multi-agency) groups in four countries: the U.S., New Zealand, Australia, & the Netherlands. Also, customized workshops for specific agencies including the US Nuclear Regulatory Agency and a selection of Australian regulators in areas including financial regulation, health, privacy and freedom of information.

Collectively, that meant that there would be roughly 1000 regulators that I would not meet—or, at least, not as planned in the immediate future. So in my second week of home isolation I started wondering what I could best do to make up for the missed opportunities to engage with them. One thing I could do, for sure, was offer the basics of what we would have discussed, in book form. I estimated that across the various courses and workshops I had scheduled, we would have typically spent 25% to 35% of the time laying out a set of fundamental dilemmas that all regulators face; that is, choices they confront in the design of their regulatory operations, dimensions along which regulatory agencies can vary substantially, critical aspects of their operations which they might conceivably want to change.

I label these introductory lectures the "Fundamentals of Regulatory Design" because they apply to everybody in the regulatory business. That does not mean that all regulators made the same design choices; just that they have all (whether they knew it or not) made these design decisions one way or another during the course of their agency's development and history. Laying these design dilemmas out—and recognizing all the permutations and combinations of choices that result when one considers them all together—can be thought of as "mapping the terrain." Taken together, these fundamental design choices combine to present a complicated surface over which regulatory agencies might move, and upon which they currently occupy some particular position. It is good to know where you are, how you got there, and why. It is also good to know what other plausible possibilities exist in one's neighborhood.

Mapping the terrain is normally just the start of the conversation. Regulators then want to understand which position on the terrain they currently occupy and the history of their own journey to that point. They also want to know what shifts in position they might

contemplate in order to respond best to pressures acting on them. Regulatory executives, therefore, feel the need to engage in customized diagnostic and analytical work. But that comes later, and proceeds more quickly and efficiently if everyone involved in those diagnostic discussions has first grasped the fundamentals and shares a clear and common vocabulary they can use to describe the choices in front of them.

Some object: "Why bother me with design options? My agency is already designed, and I'm not in a position to redesign it."

Redesign happens infrequently and usually incrementally if at all. But I am convinced it is still worth charting the terrain and understanding the landscape of opportunities. Why? Because, from time to time agencies get rattled, and when they get rattled they acquire some freedom to move. They get rattled by all kinds of things. Sometimes a scandal, a crisis, or a visible failure. Or a shift in political winds and direction. The emergence of new risks that are not well governed through current operations. A substantial increase, or decrease, in funding levels. Expansion of an agency's jurisdiction, which demands invention of new methods to meet new challenges.

It is then, when a chance for redesign or adjustment arises, that it would be useful to know—perhaps even to have decided in advance—which way you might want to move. Valuable opportunities for reform may pass too soon or lead only to confusion if agency leadership has not already decided, or does not quickly decide, what use to make of the opportunity.

The chapters that follow are written versions of my core lectures on regulatory design. I am pleased to offer them up for the sake of all those regulatory professionals I will not be meeting thanks to the pandemic. I am pleased to offer them up for everyone else who might be interested. Making these "fundamentals" broadly available in written form does mean, I imagine, that when we do eventually meet we should be able to move our conversation along faster, past these fundamental choices, and get more quickly to the diagnostic piece of the discussion and analysis of the challenges agencies currently face.

Each chapter concludes with a set of diagnostic questions readers can use to guide their own further exploration. To make the most of these it might be useful to set up a "book-club" with a group

of interested colleagues, to work out together how these ideas apply to your own agency. I would recommend taking one chapter at a time and then meeting together to work through the diagnostic exercise for that chapter. If you did that for all the chapters, then my guess is you will have come a long way towards a clearer collective understanding of where your agency sits on the terrain, and in which direction or directions you might want to move.

Whether we get to meet someday in the future, or not, I sincerely hope that exploring these fundamentals of regulatory design will act as a useful beginning for your own inquiry and exploration.

Who is invited?

Roughly half of government is invited. To make a crude distinction, roughly half of government work involves the delivery of services to citizens (e.g., education services, health services, transportation systems and infrastructure, delivering welfare supports, and so on). When work in this "customer-service" side of government is done well, recipients and beneficiaries of the services generally appreciate it and may even say "thank you."

But the other half of government work involves protecting citizens and society from a range of risks, threats, or harms. Various government agencies strive to protect citizens against crime, violence, pollution, occupational hazards, transportation hazards, fraud, corruption, product-safety risks, smuggling, terrorism, discrimination, and a host of other potential harms.

Even though agency missions align somewhat messily with the distinction between service-provision and protective duties, those most obviously involved in delivering protections include law-enforcement, security and intelligence agencies as well as virtually all agencies of social regulation.

For thirty years my professional life has focused on this *protective* half of government. This half of government is different. These agencies use the coercive power of the state, seeking to control behaviors. They deliver *obligations,* to citizens and businesses, more often than services. Acting in the public interest, they can restrict private behaviors, deprive individuals of their liberty, impose conditions on businesses, put people out of business

if necessary, and occasionally kill. Not everyone is happy about the work they do. Not everyone says "thank you."

Having worked for so many years with professional regulators, I have learned some things about them.

First, their professional roles inevitably involve conflict, which is of course stressful. Their jobs are not about pleasing everyone. To achieve their public and protective purposes, the private players they encounter are being asked to take a loss—usually to their short term, private, or economic interests.

Some of those private actors play their part more willingly than others, for sure. Nevertheless, the idea that regulation, if done well enough and in a cooperative spirit, could make all stakeholder groups perfectly happy seems far-fetched. As a matter of ordinary logic, if there were a resolution of a regulatory matter that would make all parties perfectly happy, then this issue would appear not to require regulation. Market forces and some shrewd negotiation could resolve it.

The whole point of regulation is that government needs to intervene, for the public good, when market forces and private incentives do not naturally combine to serve the public interest. The relationship between regulators and regulated is never, therefore, perfectly harmonious. Some degree of conflict is inevitable.

Second, regulators are not much appreciated, as a general rule, by the public. Particularly with respect to catastrophic risks (high impact, very low frequency events) the attitude of the public seems somewhat binary. Either there was a disaster yesterday, which from a public viewpoint must obviously involve a regulatory failure, or a *failure of vigilance*: "Why was the government asleep at the switch?" "Why did they not see this coming?" "This should and could have been prevented."

Or, there has not been a disaster of a particular type for a good long time, in which case the need for reasonable protections is forgotten and the deregulatory drumbeat inevitably begins to sound: "Regulation is suffocating the economy." "We just need less of it." "Time for a red-tape reduction campaign, to alleviate unreasonable regulatory burdens placed on industry."

It does seem, sometimes, that regulators just cannot win when it comes to building sustained public support, despite the fact that maintaining sensible levels of controls, in the presence or absence

of catastrophe, is obviously in everyone's best interests.

The third thing I have learned about professional regulators is how little practical instruction is available for them. The service side of government can learn a great deal by emulating the very best of private sector practice in relation to customer service delivery and business process management.

But who teaches regulatory practice? I find myself apologizing constantly to regulatory practitioners for academia's general neglect of them and their work; and this despite the fact that many thousands of academics worldwide engage in the study of regulation. Academics interested in regulation mostly study regulatory policy and pay hardly any attention to regulatory practice. Academic lawyers and economists work on regulatory policy. The lawyers attend to the quality and framing of the law itself. The economists help with the assessment and prioritization of risks, and with the required cost/benefit analyses that justify making new rules or scrapping old ones.

But the practitioners sit in the middle, between the law as it stands, and the state of the front-line protections as delivered to society. And what they do matters! Even once the law is set in place, practitioners confront a host of choices—not least, all the fundamental design dilemmas addressed in this book.

It matters how regulatory practitioners organize themselves, and what skills they develop. It matters when they choose to use law, and when they use other methods instead to reduce harm. It matters on what basis they target their efforts, what type of relationships they form with those they regulate, and which regulatory responses they choose to employ. It matters a great deal what data they gather and analyses they conduct, as that will affect which risks they can see and how quickly.

Regulatory practitioners use discretion every day, more likely every hour. It matters what values govern their inevitable choice-making. It matters the degree to which they choose to trust the motivations and competencies of industry. It matters which parts of the risk-control task they choose to delegate to industry, or share with them, and under what circumstances.

These are the practical, professional and managerial puzzles that regulatory practitioners wrestle with constantly.

Who else is welcome?

I am delighted to extend the invitation more broadly, to another group of folks who are not regulators per se, and many of them do not even work for government agencies. But they are nevertheless firmly in the risk-control or harm-reduction business, and they are therefore interested in a very similar set of design dilemmas as they take on, or fashion their own contributions to, the control of risks to society.

Members of professional boards belong to this broader group. Board members have been joining government regulators at my courses and seminars in increasing numbers over the last several years. Prominent among this group are members of medical Boards. When a medical professional, (e.g., a surgeon, psychiatrist, nurse, or pharmacist) by virtue of their eminence in their field, gets elected or appointed to a Board, they acquire a governance role. In that role they play a part in setting, maintaining, and enforcing standards. They have compliance and disciplinary responsibilities. Yes, the Boards to some degree exist to serve the interests of their members; but they also have a duty to protect the public from the consequences of poor-quality practice. Boards may adjudicate cases of malpractice and may on occasions exclude or disqualify people from the profession.

However eminent members of professional Boards may be within their own fields, they have not normally received formal training on how to think through the regulatory aspects of their governance roles. They will find each of these "fundamentals of regulatory design" completely relevant to their Board roles. I have always been, and remain, delighted to include this group of professionals in this discussion.

What is a Risk-Based Regulator?

Over the last few years I have often delivered these core lectures on the fundamentals of regulatory design under a different title: "What is a Risk-Based Regulator?" On occasions I have used another version which is more personally challenging: "What is a Risk-Based Regulator, and would you like to be one?"

This choice of title connects the material to contemporary language and to a set of questions that have been swirling around recently in regulatory circles. Most of the issues practitioners raise, when discussing what is or is not "risk-based regulation," fall squarely within the scope of one or another of these fundamental design dilemmas. Many of these same dilemmas were discussed a decade or two ago under the then contemporary language of "regulatory reform". The question "what kind of regulatory reform should we pursue" takes us to similar terrain and similar choices in navigating our way around it.

Notice, however, that the phrase "regulatory reform" is ambiguous. Are we talking policy or practice? Which one is being reformed? If we are to reform the regulations themselves, then we might be advancing a deregulatory agenda, or a red-tape reduction movement, or relief of regulatory burden on industry, or using "one-in one-out" rules or other devices to manage the stock of regulations, or all of these—and never once mention the conduct of regulators.

I like the fact that the question "what is a risk-based regulator" is at least unambiguous as to whether we are talking regulatory policy or practice. If the question were instead "what might it mean to have risk-based regulation (or regulations)" then we would know we were discussing the law, regulations, or written policies and guidelines. But a "risk-based regulator" is either a person or an agency, and so the discussion must be about practice—that is, how a regulator, once the regulations are in place, might act in a risk-based manner. So far, unfortunately, discussions about "risk-based regulation" seem to have focused more on what it means for the regulations themselves to be risk-based, and less on how a risk-based regulator might act at an operational level.

Once we focus unambiguously on the conduct of regulators, the phrase "risk-based regulator" still has a multitude of potential interpretations.

For some, a risk-based regulator is simply one that "focuses their resources and efforts on the most serious risks." That seems appealingly obvious and straightforward. But others might question whether that is really new, or whether it was always the case. Or they might point out that the devil is in the details and ask what practical effect such a broad principle will have on operational strategy and tactics.

Some—especially within the regulated industry—hope that their regulators, adopting a risk-based philosophy, will exhibit a higher tolerance for residual risk and therefore bother them less over trivial matters and minor non-compliance.

Many regulators assume that a risk-based approach involves adopting a *risk-based targeting system* to govern traditional audit and inspection programs. They will still carry out the same kind of standardized audits, or inspections, or investigations—but what changes is where they will choose to go, and how often. The agency might develop a risk-scoring system, which then ranks potential firms or facilities in terms of their comparative riskiness. Instead of scheduling inspections routinely, or randomly, or alphabetically—or however they were done before—the risk-based regulator now picks their targets off the top of a rank-ordered list.

Another potential subtlety might involve changing the nature of the audits or inspections, even after a risk-based targeting methodology has been used in selecting the site. Maybe a risk-focused audit is different from a standard or routine one, more tailored to specific issues, potentially honing in on problem areas identified in advance of the site visit.

A completely different idea is that being risk-based changes the nature of the relationship that regulators have with the entities they regulate. Regulators could delegate more of the responsibility for risk identification and control to industry, potentially de-emphasizing compliance with prescriptive rules. Some regulators (especially in Europe) associate risk-based practice with the adoption of "light-touch, trusting, self-regulatory regimes" presuming that to be the modern way. In some settings, risk-based regulation is closely associated with the adoption of Safety Management Systems.

All these various possibilities lie comfortably within the scope of the fundamentals of regulatory design that the following chapters address. For now, within this book at least, I will stick to the language *fundamentals of regulatory design* because that language seems more abiding. These basic choices will outlast the contemporary language. With any luck, the book will do that too!

The good news, for readers who remain genuinely curious to know what is a risk-based regulator, is that I am not shelving or ducking that question. For each design dilemma addressed we will

ask, towards the end of each chapter: "Given this particular framework, and in the context of this particular dimension of choice, what might it mean to be a risk-based regulator?" The answers will be different for each chapter, as each chapter addresses a different dimension of choice. That way we will end up with several distinct and clearly delineated versions of what risk-based practice might mean.

Holding these several distinct ideas about risk-based regulation in mind, simultaneously, will hopefully help next time someone proposes that your agency should adopt a risk-based approach. At least you can inject some needed clarity into the conversation: "Well let's be clear, which of the several different versions of risk-based practice are we talking about here?" Maybe we need one of them, but not another. Maybe we should adopt several, simultaneously, assuming they fit together. I would like to think that clearer differentiation of the choices makes such conversations more productive. Regulators can then choose to be risk-based, and un-befuddled, at the same time!

Once more, on behalf of academia, I apologize for the general lack of serious attention paid to regulatory practice. I hope this book helps to plug the gap and demonstrate that regulatory practice is a subject worthy of serious study.

I hope we will have a chance to meet someday to discuss these matters. In the meantime, please accept my "stay at home" offering.