

Regulatory Priority-Setting and Problem-Solving: "Data-Driven," "Risk-Based," "Right-Touch"

Cary Coglianesse, J.D., M.P.P., Ph.D.

Edward B. Shils Professor of Law and Political Science

Director, Penn Program on Regulation

University of Pennsylvania Law School

National Council of State Boards of Nursing

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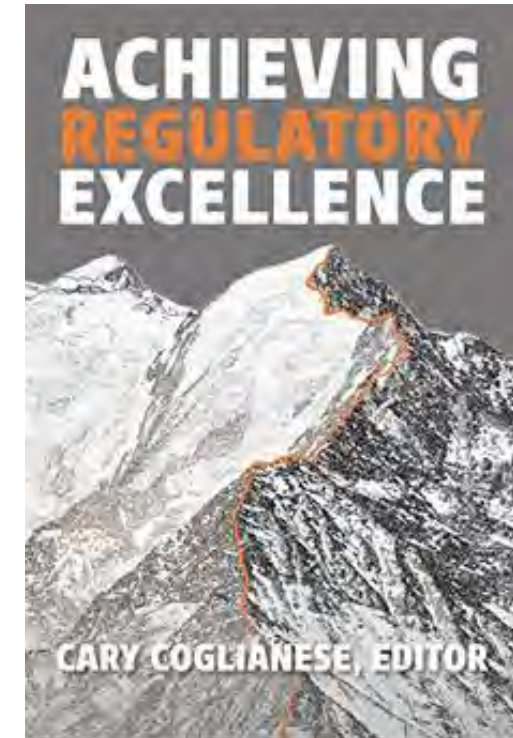
**PENN PROGRAM
ON REGULATION**
UNIVERSITY of PENNSYLVANIA

Why seek excellence in regulatory priority-setting and problem-solving?



Because “lives are on the line...”

“We also face daunting expectations ... The steps are often uncertain. The knowledge to be mastered is both vast and incomplete. Yet we are expected to act with swiftness and consistency ... We are also expected to do our work humanely, with gentleness and concern.”



“Gawande could just as well have been writing about regulators.”

What Does Regulatory Success Look Like?

Failures are More Visible than Successes

Nebraska nurse has her license revoked for prescribing weight-loss drugs illegally

State report: Local nurse loses license over sexual misconduct with anesthetized patients

Bellevue nurse gets license revoked, accused of committing gross negligence

PRACTICAL NURSE LICENSE REVOKED

- ▶ Petition filed by the Nebraska Attorney General's office
- ▶ Alleges Curlee Schneiders instructed an assistant to give a patient a snack inconsistent with his soft diet
- ▶ Patient choked



Williamson County nurse loses license for sexually explicit texts to patients, records say

Missouri nurse loses license, banned for life after forging opioid prescriptions



WSMV4 FOLLOW UP

FORMER NURSE LICENSE SET TO STAY REVOKED

RADONDA VAUGHT GAVE PATIENT FATAL DOSE OF WRONG MEDICATION

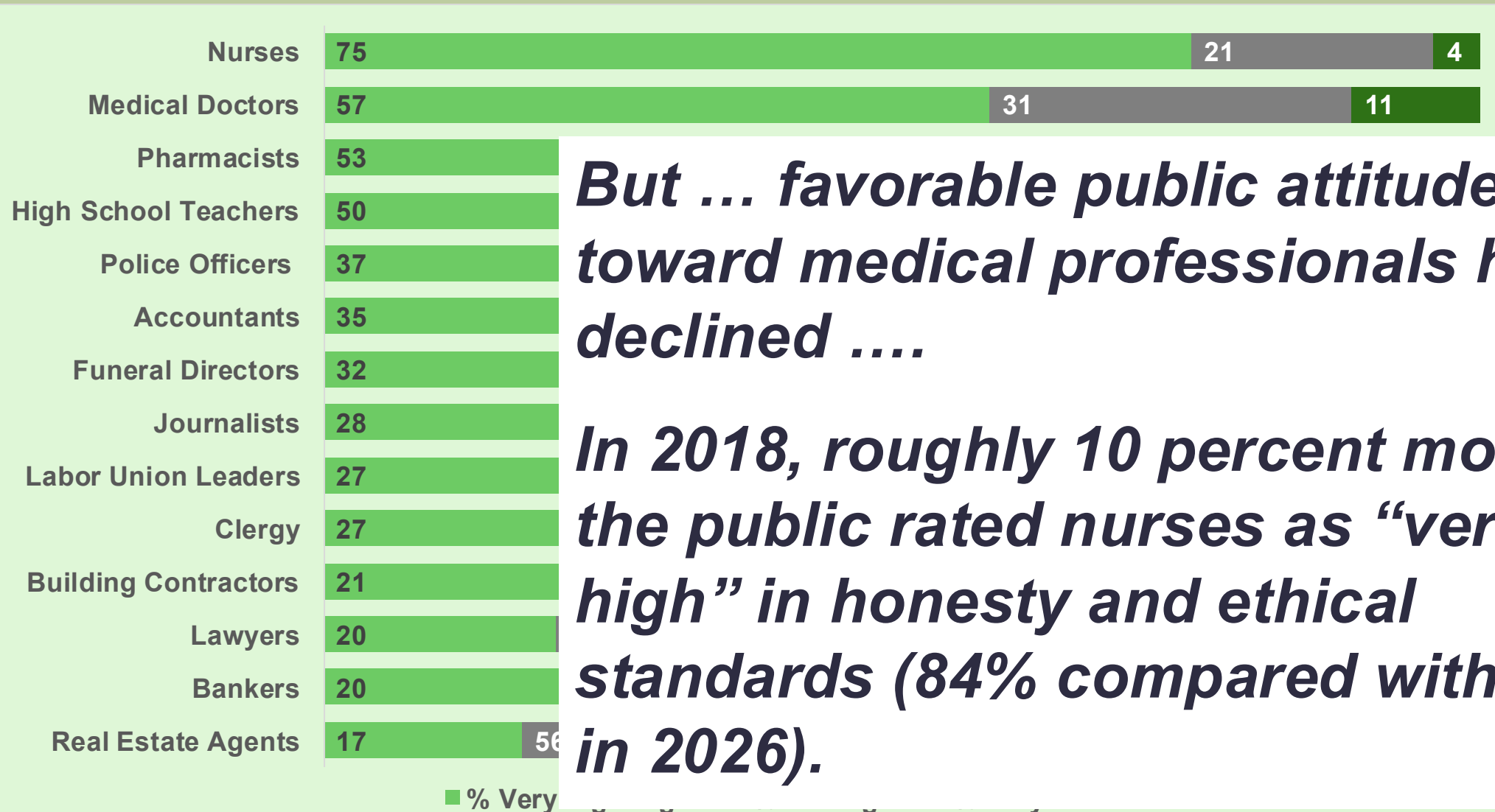
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WSMV

New Jersey nurse loses license after luring two women to the US, taking their passports, and forcing them into labor

Bolaji Bolarinwa, 51, of Moorestown, lost her nursing licenses for luring victims, confiscating their documents, and forcing them into around-the-clock domestic work

Public Perceptions of Medical Professionals



But ... favorable public attitudes toward medical professionals have declined

In 2018, roughly 10 percent more of the public rated nurses as “very high” in honesty and ethical standards (84% compared with 75% in 2026).

The Complexity of Regulating



Arête: Excellence



What Makes for an *Excellent* Regulator?



Listening • Learning • Leading

A Framework for Regulatory Excellence

Cary Coglianese



PENN PROGRAM ON
REGULATION

“In searching after one virtue
we have found many.”

— SOCRATES

Virtues of “Right-Touch” Regulation

- 1. Proportionate:** regulators should only intervene when necessary. Remedies should be appropriate to the risk posed, and costs identified and minimised.
- 2. Consistent:** rules and standards should be joined up and implemented fairly. Regulators should work for consistent outcomes with disparity only where this can be justified.
- 3. Targeted:** regulation should be focused on the problem it is seeking to solve, and minimise unwanted side effects.
- 4. Transparent:** regulators should work openly, be accessible to scrutiny, and keep regulations simple and user-friendly.
- 5. Accountable:** regulators must work transparently, and be open and accessible to scrutiny.
- 6. Agile:** regulators must look forward, anticipating and adapting to change.

Text from PSA (2025)



Many Other Attributes of Regulatory Excellence

APPENDIX B: ATTRIBUTES OF REGULATORY EXCELLENCE

Alberta Energy Regulator (2014)

1. Protective
2. Effective
3. Efficient
4. Credible

Australian Communications and Media Authority (2013)

1. Bridging to the Future
2. Transforming the Agency
3. Major program delivery
4. Effective regulation

Brown, et al (2006)

1. Independence
2. Accountability
3. Transparency and Public Participation
4. Predictability
5. Clarity of Roles
6. Completeness and Clarity in Rules
7. Proportionality
8. Requisite Powers
9. Appropriate Institutional Characteristics
10. Integrity

Environment Canada (2012)

1. Evidence based decision making
2. Effectiveness
3. Efficiency
4. Transparency
5. Adaptability

Farrell & Goodman (2013)

1. Use of better evidence for decision-making
2. Greater engagement and empowerment of citizens
3. Thoughtful investments in expertise and skill building
4. Closer collaboration with the private and social sectors

Gardner, et al (2013)

1. Accelerating ... strategic goals
2. Using efficient and transparent processes
3. Strengthening capabilities
4. Building expertise
5. Providing customers with cross-functional support
6. Working as a coordinated and cohesive internal team

Government of Alberta (2010)

1. Effective
2. Efficient
3. Adaptable
4. Predictable
5. Fair
6. Transparent

Hempling, Scott (2013)

1. Purposeful
2. Educated
3. Decisive
4. Independent
5. Disciplined
6. Synthesizing
7. Creative
8. Respectful
9. Ethical

Mumford, Peter (2011)

1. Growth supporting
2. Proportional
3. Flexible and Durable
4. Certain and predictable
5. Transparent and accountable
6. Capable Regulators

New Zealand Ministry of Business, Innovation & Employment (2011)

1. Efficiency
2. Effectiveness
3. Transparency
4. Clarity
5. Equity

New Zealand Treasury (2012)

1. Growth supporting
2. Proportional
3. Flexible
4. Durable
5. Certain and predictable
6. Transparent and accountable
7. Capable Regulators

OECD (2005)

1. Adopt at the political level broad programmes of regulatory reform that establish clear objectives and frameworks for implementation.
2. Assess impacts and review regulations systematically to ensure that they meet their intended objectives efficiently and effectively in a changing and complex economic and social environment.
3. Ensure that regulations, regulatory institutions charged with implementation, and regulatory processes are transparent and non-discriminatory.
4. Review and strengthen where necessary the scope, effectiveness and enforcement of competition policy.
5. Design economic regulations in all sectors to stimulate competition and efficiency, and eliminate them except where clear evidence demonstrates that they are the best way to serve broad public interests.
6. Eliminate unnecessary regulatory barriers to trade and investment through continued liberalization and enhance the consideration and better integration of market openness throughout the regulatory process, thus strengthening economic efficiency and competitiveness.
7. Identify important linkages with other policy objectives and develop policies to achieve those objectives in ways that support reform.

OECD (2012)

1. Commit at the highest political level to an explicitly whole-of-government policy for regulatory quality.
2. Adhere to principles of open government, including transparency and participation in the regulatory process to ensure that regulation serves the public interest and is informed by the legitimate needs of those interested in and affected by regulation.
3. Establish mechanisms and institutions to actively provide oversight of regulatory policy procedures and goals, support and implement regulatory policy, and thereby foster regulatory quality.

4. Integrate Regulatory Impact Assessment (RIA) into the early stages of the policy process for the formulation of new regulatory proposals.

5. Conduct systematic programme reviews of the stock of significant regulation against clearly defined policy goals, including consideration of costs and benefits, to ensure that regulations remain up to date, cost justified, cost effective and consistent, and deliver the intended policy objectives.

6. Regularly publish reports on the performance of regulatory policy and reform programmes and the public authorities applying the regulations.

7. Develop a consistent policy covering the role and functions of regulatory agencies in order to provide greater confidence that regulatory decisions are made on an objective, impartial and consistent basis, without conflict of interest, bias or improper influence.

8. Ensure the effectiveness of systems for the review of the legality and procedural fairness of regulations and of decisions made by bodies empowered to issue regulatory sanctions. Ensure that citizens and businesses have access to these systems of review at reasonable cost and receive decisions in a timely manner.

9. As appropriate apply risk assessment, risk management, and risk communication strategies to the design and implementation of regulations to ensure that regulation is targeted and effective.

10. Where appropriate promote regulatory coherence through co-ordination mechanisms between the supranational, the national and sub-national levels of government.

11. Foster the development of regulatory management capacity and performance at sub-national levels of government.

12. In developing regulatory measures, give consideration to all relevant international standards and frameworks for co-operation in the same field and, where appropriate, their likely effects on parties outside the jurisdiction.

13. Adopt at the political level broad programmes of regulatory reform that establish clear objectives and frameworks for implementation.

14. Assess impacts and review regulations systematically to ensure that they meet their intended objectives efficiently and effectively in a changing and complex economic and social environment.

15. Ensure that regulations, regulatory institutions charged with implementation, and regulatory processes are transparent and non-discriminatory.

16. Review and strengthen where necessary the scope, effectiveness and enforcement of competition policy.

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19. Identify important linkages with other policy objectives and develop policies to achieve those objectives in ways that support reform.

Riefberg, et al (2013)

1. Clear articulation of strategy and overall agency direction
2. Well defined operating model based on efficient and effective processes and systems

3. Organizational culture that harnesses the unique talents of employees and steers those talents towards achieving the agency's mission

Texas Department of Insurance (2011)

1. Timely
2. Prompt
3. High-quality
4. Efficient
5. Accurate
6. Limited Disputes/Prompt Resolution
7. Cost-Effective

Treasury Board of Canada Secretariat (2012)

1. Protect and advance the public interest
2. Advance efficiency and effectiveness
3. Make decisions based on evidence
4. Promote a fair and competitive market economy.
5. Monitor and control the administrative burden.
6. Create accessible, understandable & responsive regulation
7. Require timeliness, policy coherence and minimal duplication

UK Civil Service (2009)

1. Set direction (Leadership)
2. Ignite passion, pace and drive (Leadership)
3. Develop People (Leadership)
4. Set strategy and focus on outcomes (Strategy)
5. Base choices on evidence and customer insight (Strategy)
6. Collaborate and build common purpose (Strategy)
7. Innovate and improve delivery (Delivery)
8. Plan, resource and prioritize (Delivery)
9. Develop clear roles, responsibilities & delivery model(s) (Delivery)
10. Manage performance and value for money (Delivery)

UK Department of Energy and Climate Change (2009)

1. Set direction (Leadership)
2. Ignite passion, pace and drive (Leadership)
3. Take responsibility for leading delivery and change (Leadership)
4. Build Capacity (Leadership)
5. Focus on Outcomes (Strategy)
6. Base choices on evidence (Strategy)
7. Build common purpose (Strategy)
8. Plan, resource and prioritize (Delivery)
9. Develop clear roles, responsibilities & delivery model(s) (Delivery)
10. Manage performance (Delivery)

UK Environment Agency (2013)

1. Proportionate
2. Targeted
3. Customer-focused
4. Consistent
5. Accountable

UK Food Standards Agency (2005)

1. Delivering outcomes
2. Practical and timely interventions
3. Consistent, risk-based, proportionate and transparent decision-making
4. Using the market & applying effective incentives & sanctions
5. Continuous learning
6. Delivering value for money
7. Changing the landscape

Source: Appendix B to Cary Coglianese, *Listening and Learning: Toward a Framework of Regulatory Leadership* (2015)

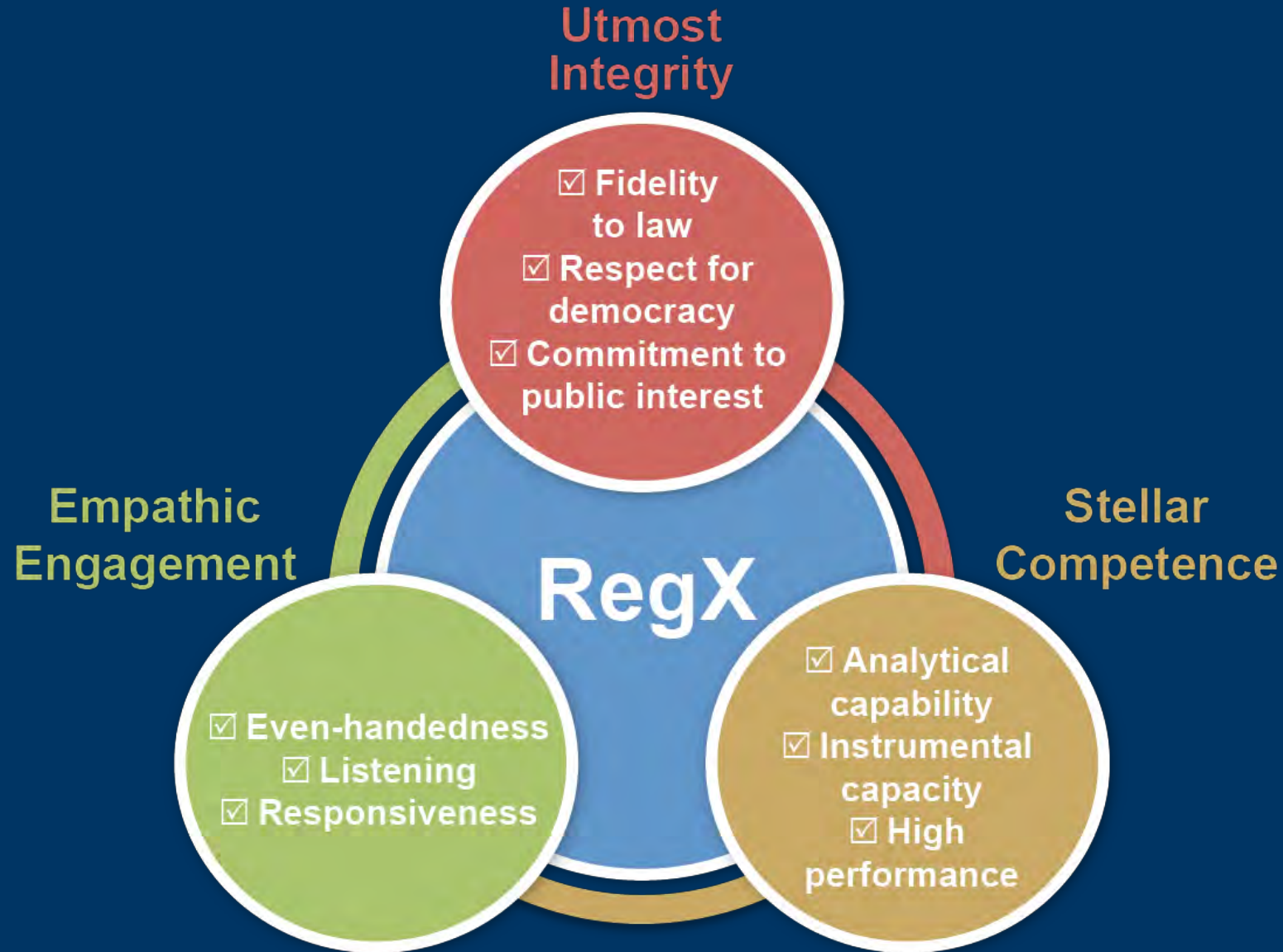


Source: Coglianesi & Scheffler (2016)

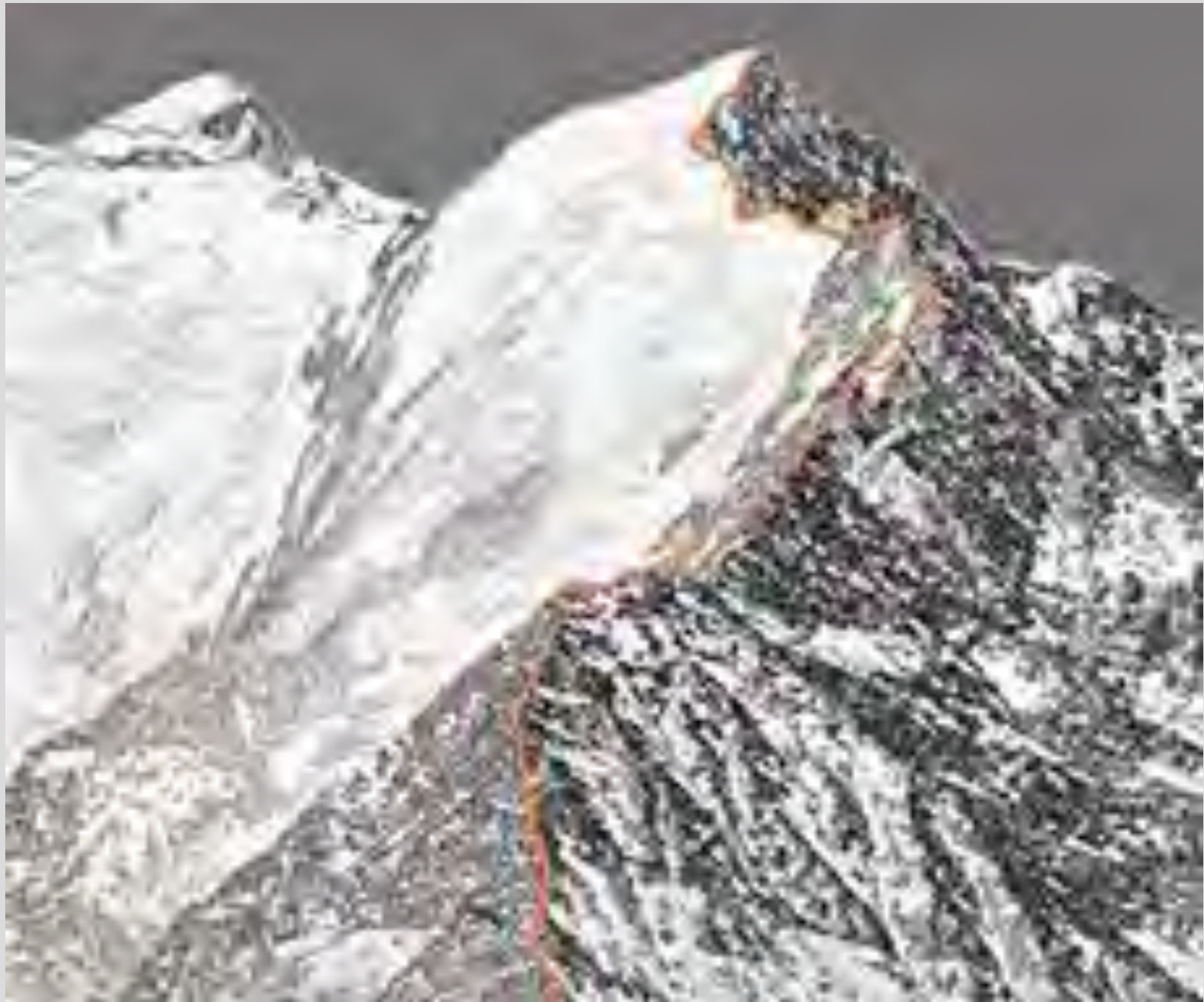
RegX: Atoms of Excellence



Nine Tenets of Regulatory Excellence

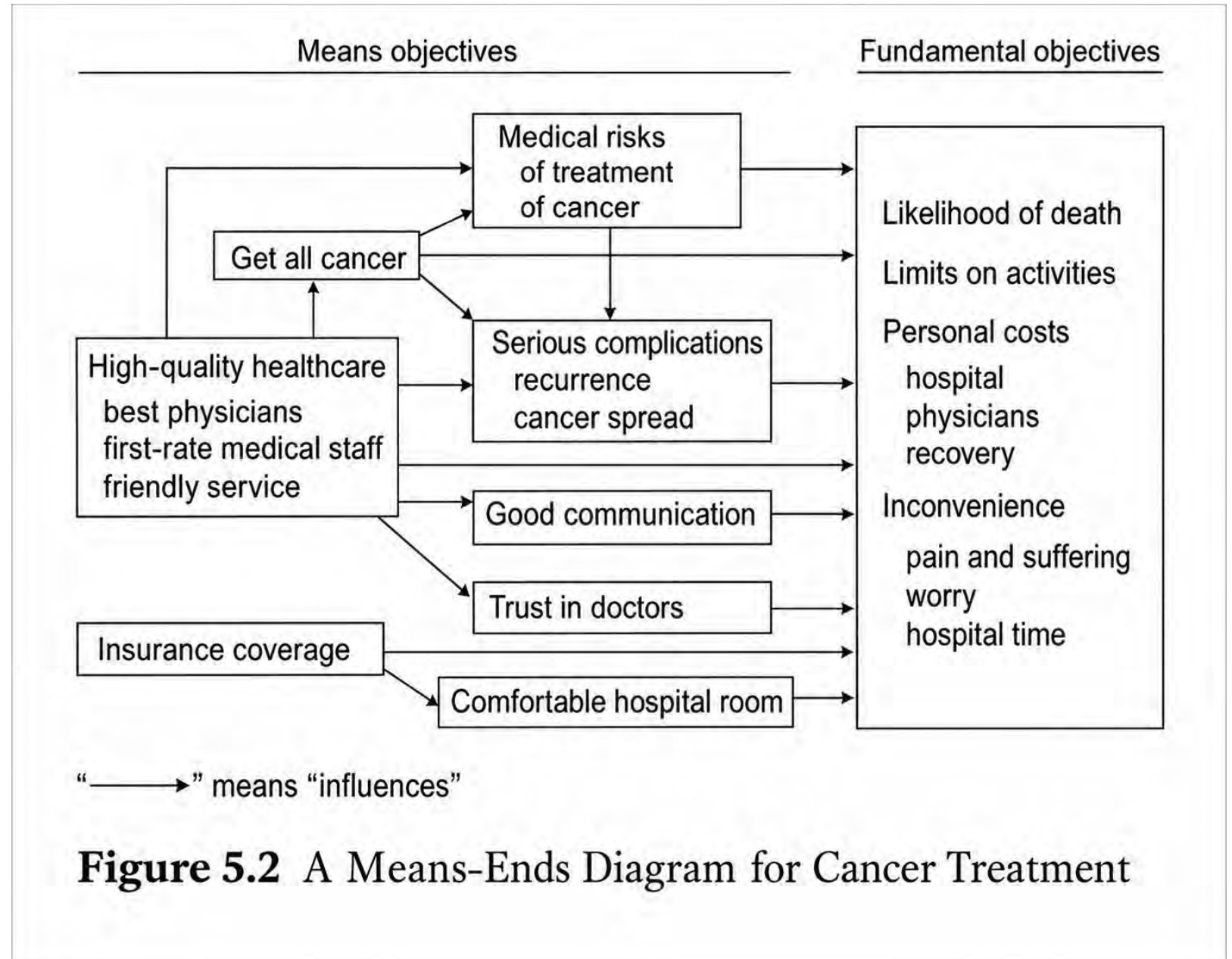


Achieving Regulatory Excellence

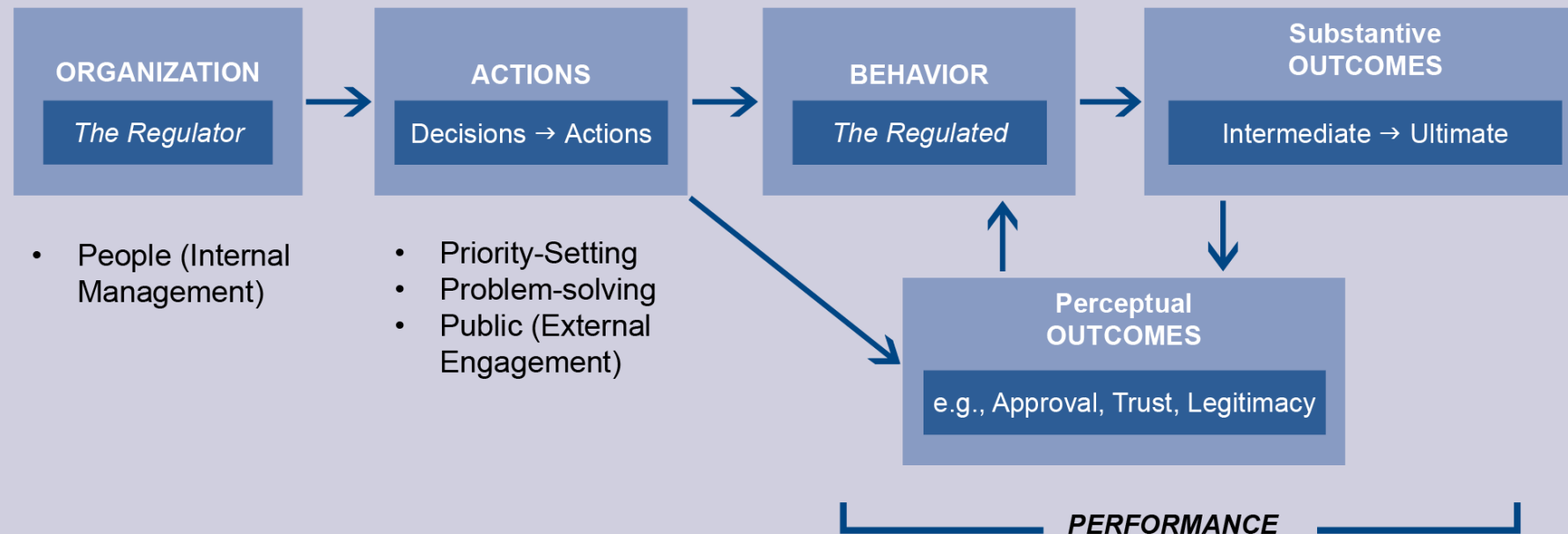


Means → Ends in Medical Care

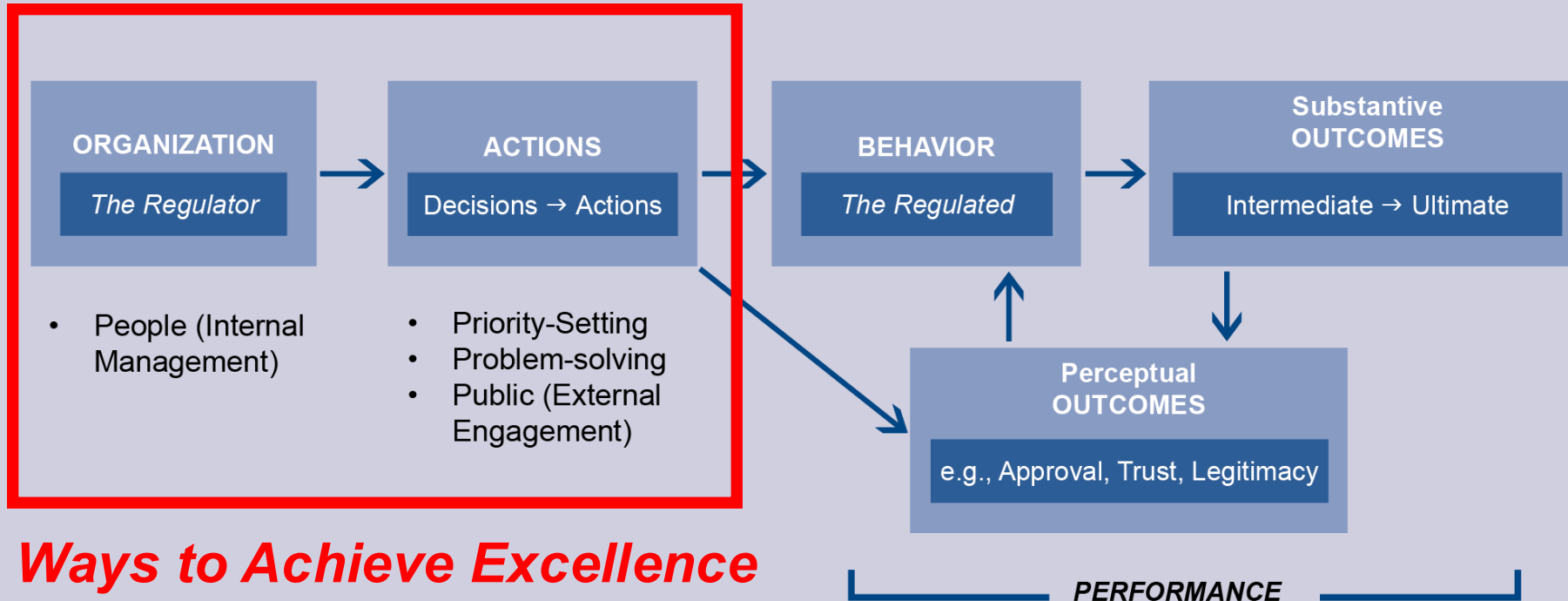
Ralph L. Keeney, *Value-Focused Thinking: A Path to Creative Decisionmaking* (Harvard University Press 1992)



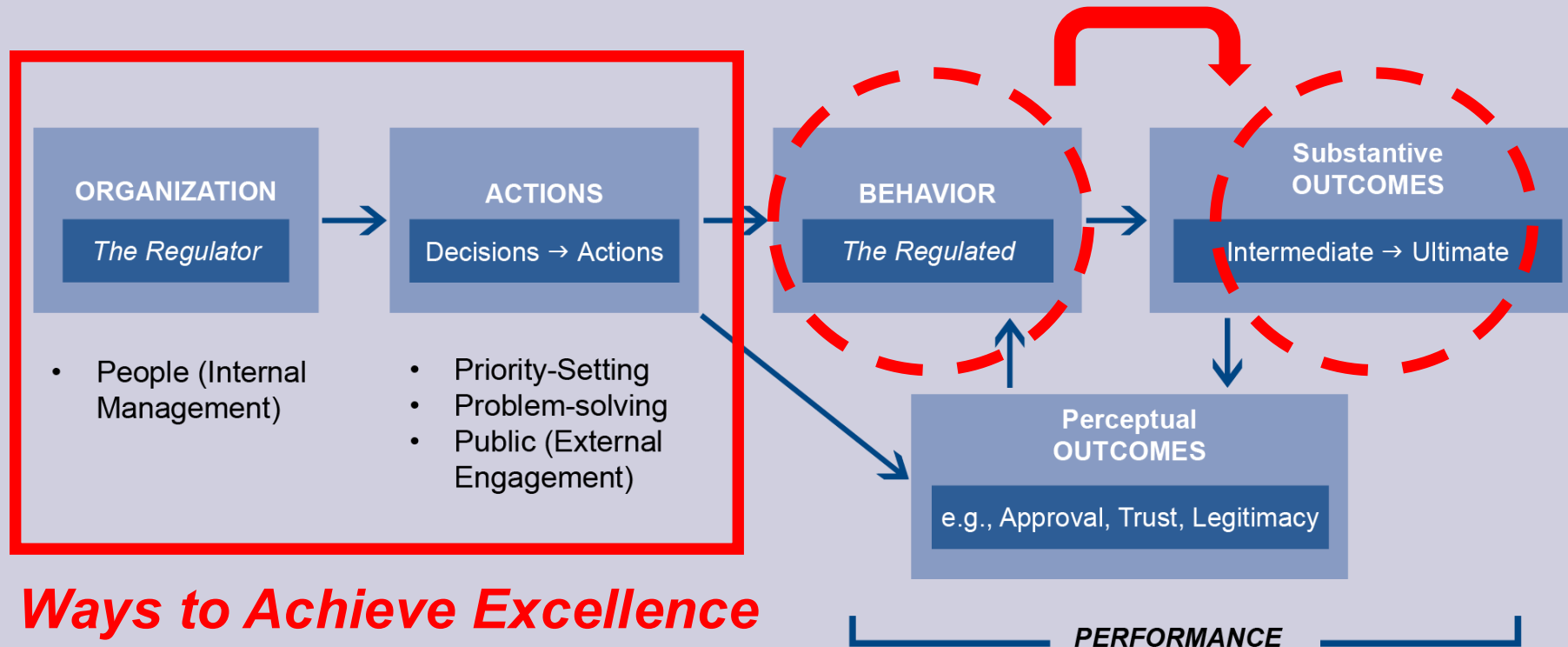
Means-End Model of Regulatory Performance



Means-End Model of Regulatory Performance



Means-End Model of Regulatory Performance



[Opinion](#) | [Process](#) | Feb 12, 2024

Compliance is the Bridge to Better Regulatory Outcomes

Cary Coglianese



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Analyzing and improving compliance is the key to strengthening regulators'



These doors must be
closed at all times

These doors must be
closed at all times

Compliance through Enforcement

“20% of the regulated population will ***automatically comply*** with any regulation, 5% will ***attempt to evade*** it, and 75% will comply so long as ***they think that the 5% will be caught*** and punished.”

- Quote commonly attributed to Chester Bowles, U.S. public leader and Administrator, Office of Price Administration, 1943-1946

[Note: the percentages were not based on anything but a hunch on Bowles' part (and they referred to individuals, not businesses), so they should not be taken as precise or applicable to all contexts, but the three types of regulated entities he describes exist.]

REGULATORY REFORM

Revisiting Bowles's Aphorism

Improving regulatory compliance requires more than just going after “bad apples.”

✚ BY CARY COGLIANESE

Well-designed regulations seek to correct for market failures. But they can only protect society if they are followed. For decades, an assumption has prevailed throughout regulatory circles that most businesses are willing to comply with most regulations as long as regulators go after the relatively few truly bad actors. After all, regulated companies don't want to be made a sucker for following the

at a Canadian standards body apparently think so much of the aphorism that they have placed it on their organization's homepage. To say that Bowles's quip has been “oft-quoted” would be an understatement.

WHAT BOWLES REALLY MEANT

Of course, it's hard to disagree with the idea that different firms will have different propensities to comply with regulations. But

Why Do People & Firms Comply?

1. Intrinsic tendency to follow orders

- “Give me your cell phone” study (Sommers & Bohn, 2019)
- Milgram experiments

2. Legitimacy of the law

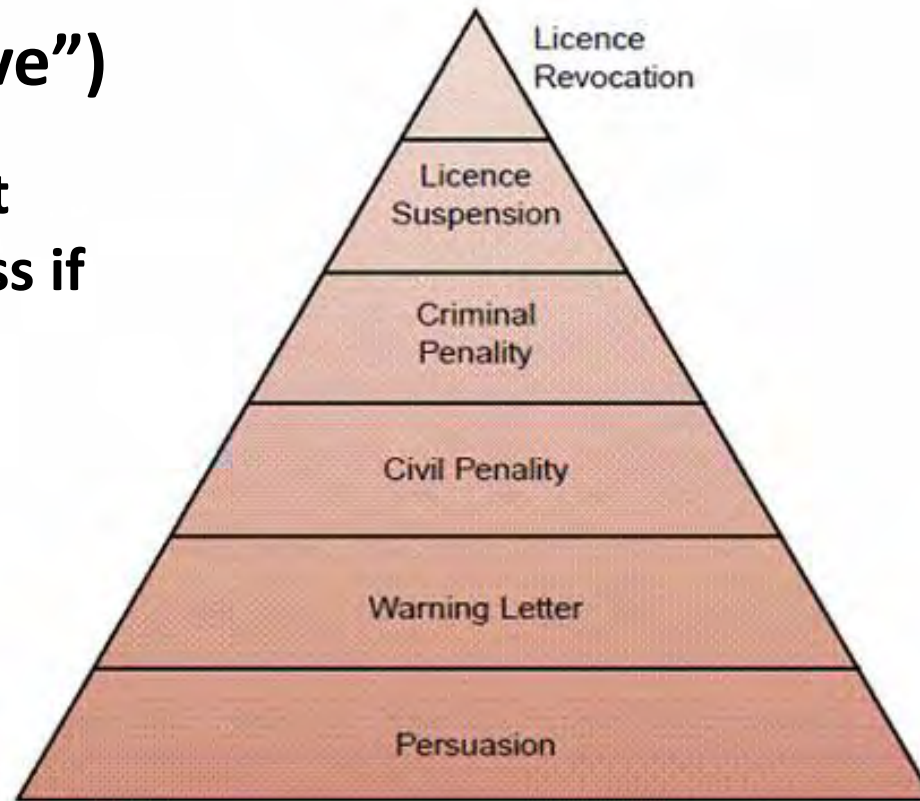
- Tom Tyler’s procedural justice research
- Malesky & Taussig study of Vietnam firms

3. Deterrence

- Specific – targeted punitive threat
- General – general threat (*see* Bowles)

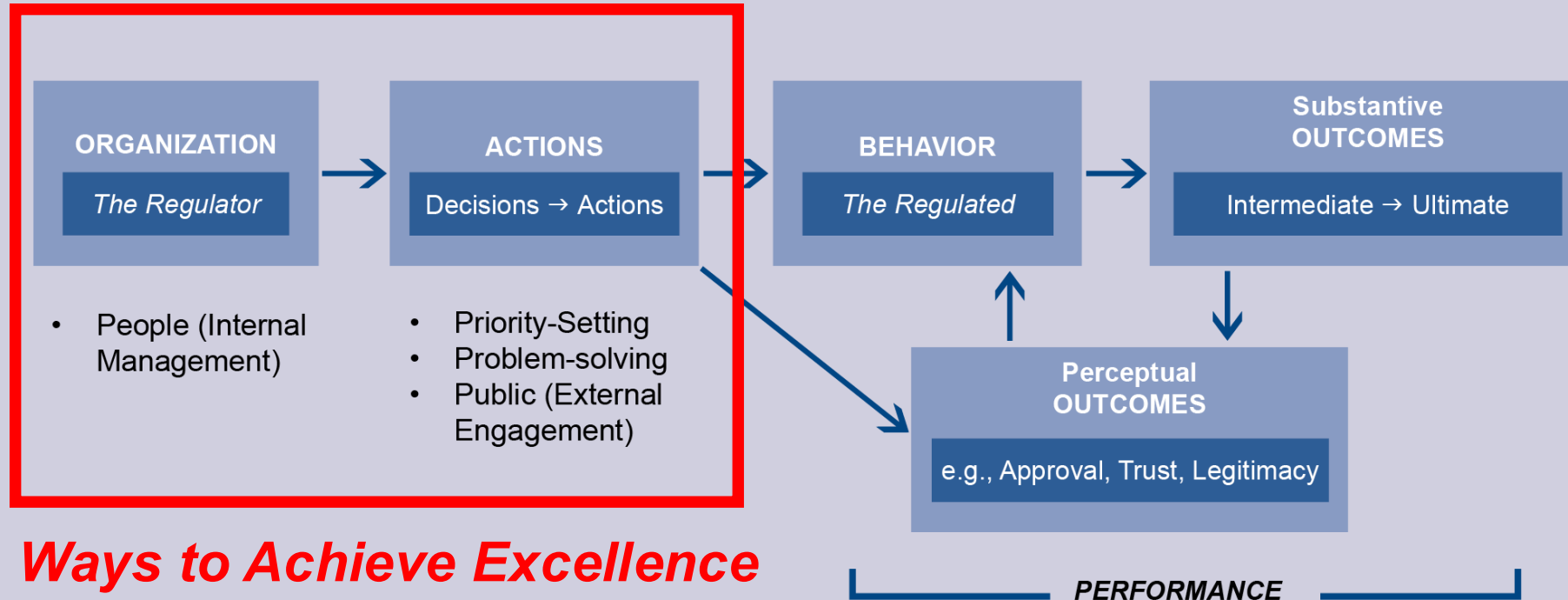
Regulator Enforcement Styles

1. Problem-solving (“advice & persuasion”)
2. Adversarial (“deterrence”)
3. Tit-for-tat (“responsive”)
 - Start cooperatively, but increase adversarialness if cooperation is not reciprocated
 - Follow “pyramid of sanctions”



Source: Ayres and Braithwaite (1992).

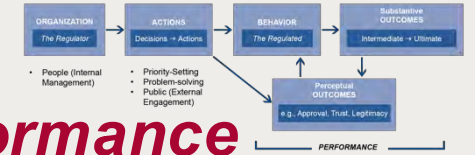
Means-End Model of Regulatory Performance



Journeying to Regulatory Excellence

1. **Self-awareness:** *build out your model*
2. **Scoping:** *assess current alignment with RegX*
3. **Select strategic priorities:** *identify key areas to improve*
4. **Assessment and continuous improvement:** *measure and move forward!*

Excellence Scoping



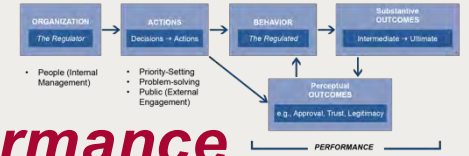
Model of Regulatory Performance

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Attributes & Tenets of Regulatory Excellence



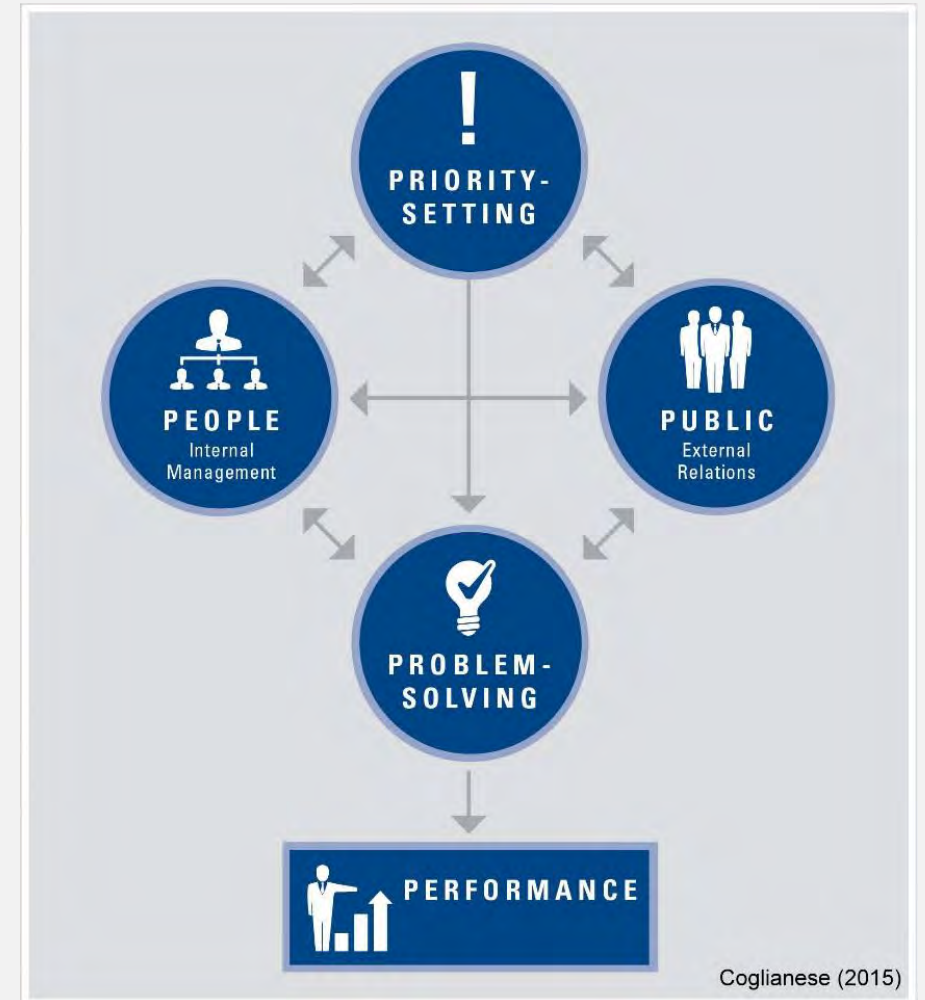
Attributes & Tenets of Regulatory Excellence



	Organization					Actions					Performance			
	Mission	Resources	Human capital	Autonomy	Culture	Decision-making	Public Engagement	Rule-making	Rule-application	Incident response	Evaluation	Industry Behavior	Perpetual Outcomes	Substantive Outcomes
Utmost Integrity	Green	Yellow	Green	Green	Green	Green	Green	Yellow	Green	Green	Yellow	Green	Green	Green
Fidelity to law	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
Respect for democracy	Yellow	Green	Yellow	Yellow	Yellow	Yellow	Green	Yellow	Green	Green	Yellow	Yellow	Green	Yellow
Commitment to Public Interest	Green	Yellow	Green	Yellow	Yellow	Green	Yellow	Green	Yellow	Green	Yellow	Yellow	Yellow	Yellow
Empathetic Engagement	Yellow	Green	Yellow	Yellow	Green	Yellow	Yellow	Green	Yellow	Yellow	Green	Yellow	Green	Yellow
Even-handedness	Green	Yellow	Green	Yellow	Green	Green	Yellow	Yellow	Green	Green	Red	Yellow	Yellow	Yellow
Listening	Green	Green	Yellow	Green	Yellow	Green	Yellow	Red	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow
Responsiveness	Yellow	Yellow	Green	Green	Red	Yellow	Green	Green	Yellow	Yellow	Green	Yellow	Green	Yellow
Stellar Competence	Green	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Green	Yellow	Yellow	Red	Yellow	Yellow	Yellow
Analytical capability	Yellow	Red	Yellow	Red	Yellow	Yellow	Red	Yellow	Red	Yellow	Green	Yellow	Red	Yellow
Instrumental capacity	Yellow	Red	Red	Yellow	Green	Yellow	Green	Yellow	Yellow	Yellow	Red	Yellow	Green	Yellow
High performance	Yellow	Red	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Red	Yellow	Yellow	Red	Yellow	Green

Keys to Achieving Regulatory Excellence

- **People (Internal Management)**
 - Mission, resources, human capital, autonomy, culture
- **Priority-setting**
 - Decision-making (risk- & evidence-based)
- **Problem-solving**
 - Rule-making, rule application, incident response, evaluation
- **Public (External Engagement)**
 - Empathy, outreach, responsiveness



Priority-setting

1. Does your organization seek out state-of-the-art evidence before making both regulatory and management decisions, and then incorporate that evidence in good faith into its decision-making and its reasons for its decisions?
2. Does your organization actively investigate and seek to generate new knowledge of poorly understood risks, potential areas of concern, and regulatory impacts?
3. Does your organization have in place adequate procedures for preserving the integrity of scientific information, including suitable processes of peer review?
4. Does your organization ground its decisions on a solid understanding of the industry/profession it is regulating, including an ongoing awareness of technological innovations?
5. Does your organization understand and articulate clearly the normative principles it uses in combination with risk analysis to make decisions (i.e., what it means to be “risk-based” or “risk-informed”)?
6. Does your organization engage in analysis of its own rules and practices, including rigorous causal evaluation, to learn what works and what could work better?

Problem-solving

1. Does your organization consistently determine that new regulations are needed (and that non-regulatory solutions would not be effective) before adopting new rules and directives?
2. Does your organization select and apply regulatory instruments that equitably maximize net benefits (or, if specified by law, that meet other policy criteria)?
3. Does your organization consider a full range of regulatory instruments that will best achieve relevant policy goals, including when appropriate, regulatory instruments that preserve flexibility?
4. Does your organization target its investigations in such a manner as to maximize the chance of finding and reducing significant regulatory violations?
5. Does your organization deploy enforcement tools responsively, calibrating consequences so as to assure compliance and promote positive cooperation?
6. Does your organization manage its own operations with efficiency, minimizing unwarranted delays in decision-making?

Threats to Sound Problem-Solving

- “Garbage-can” decisions
- Myopia
- NIMTOF
- Organizational overlaps
- Regulatory capture
- Cultural, racial biases



The excellent regulator cultivates an “over-the-horizon imagination.”

- John Braithwaite (2016)

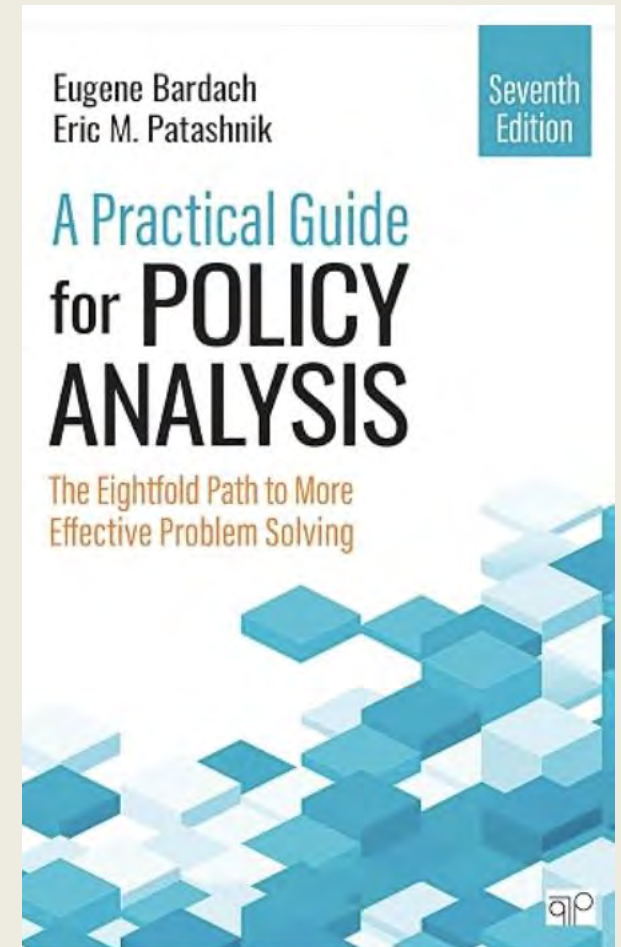
Case Example: Child Resistant Packaging



Analysis for Problem-Solving

- 1. Define and Understand the Problem**
- 2. Identify Alternative Solutions**
- 3. Select Analytic Criteria**
- 4. Analyze Alternatives Using Criteria**
- 5. Make Decision**
- 6. Implement Decision*
- 7. Evaluate Performance*

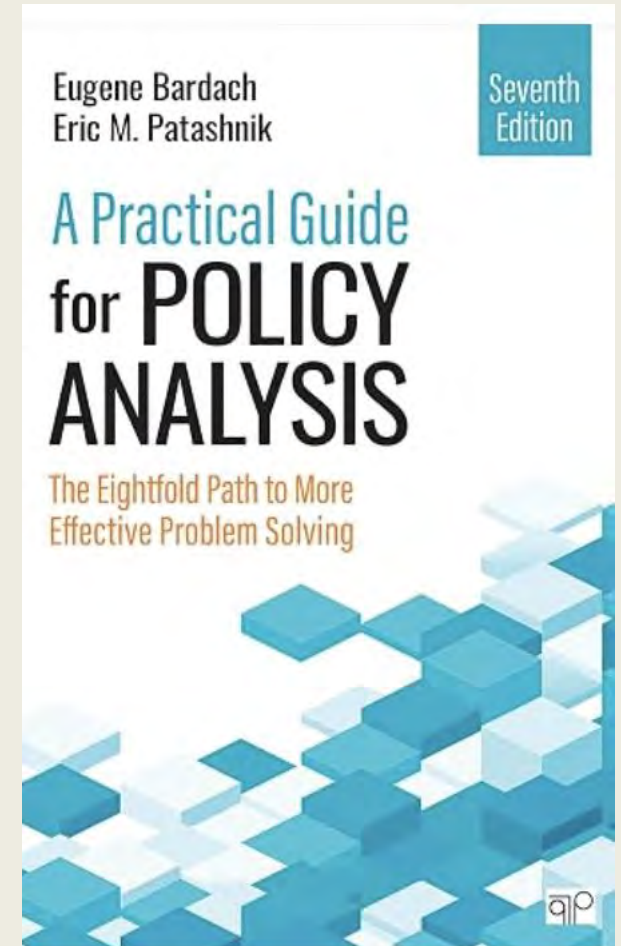
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Analysis for Problem-Solving

1. Define and Understand the Problem
2. Identify Alternative Solutions
3. Select Analytic Criteria
4. Analyze Alternatives Using Criteria
5. Make Decision
6. *Implement Decision*
7. *Evaluate Performance*

Adapted from:



Not All of a Regulator's Solutions Are *“Regulatory”*



- Warnings, alerts
- Public education
- Education of regulatees
- Hotlines
- Letters, phone calls
- Intermediaries & consensus standards
- Voluntary programs
- Certifications, rewards

And even *regulatory* solutions have alternatives.....

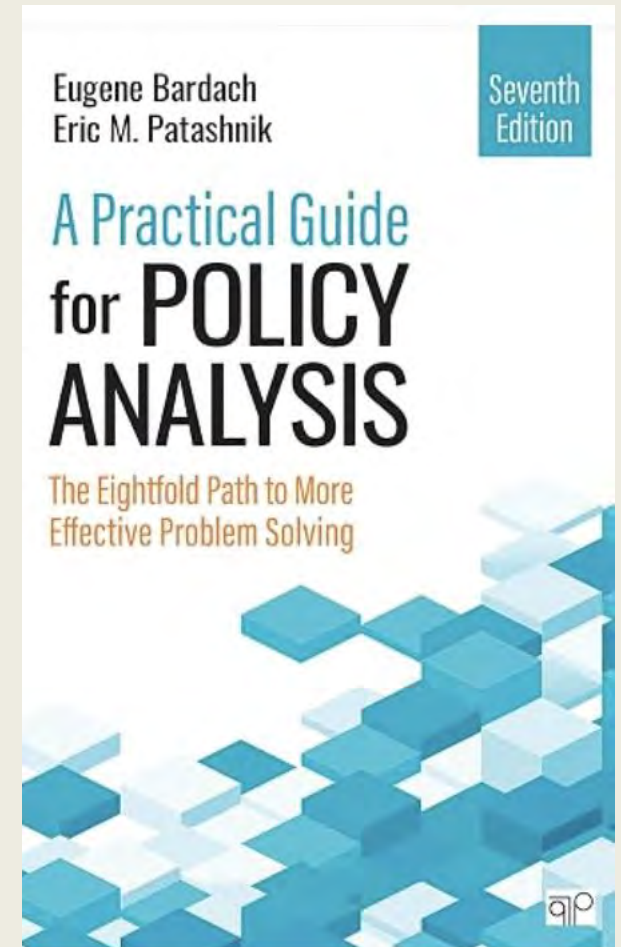
- Alternative rule designs / structures
- Alternative rule stringencies
- Alternative enforcement strategies
 - Targeting
 - Investigation techniques
 - Responses to noncompliance



Analysis for Problem-Solving

1. Define and Understand the Problem
2. Identify Alternative Solutions
3. **Select Analytic Criteria**
4. Analyze Alternatives Using Criteria
5. Make Decision
6. *Implement Decision*
7. *Evaluate Performance*

Adapted from:



Criteria for Problem-Solving

- Criteria can be used for programs, policies, procedures, practices: **any** choices!
- Criteria can be use **prospectively** in making decisions in advance, or **retrospectively** in evaluating programs, policies, procedures, practices
- It will always be relevant to use the criterion of **impact** or **effectiveness** (that is, solving the core problem or ultimate outcome of concern, or achieving your goal). The harder question will be “What other criteria to include?”

Common Criteria Other than Effectiveness

- **Cost-effectiveness**

- Lowest cost option for attaining goal
- Or, lowest cost-per-unit of problem solved
- Costs are *considered*, but not balanced against benefits

- **Efficiency / Net benefits (benefits—cost)**

- *Most efficient option is the one that maximizes net benefits*
- *Avoid benefit-cost ratios:*
 - *A 3:1 solution is not better in terms of net benefits than a 200:100 one!*

Is Benefit-Cost Analysis Inevitable?

Benefit-cost-analysis “is nothing more than a logical attempt to weigh the pros and cons of a decision. And ultimately, something like it must necessarily be employed in any rational decision.”

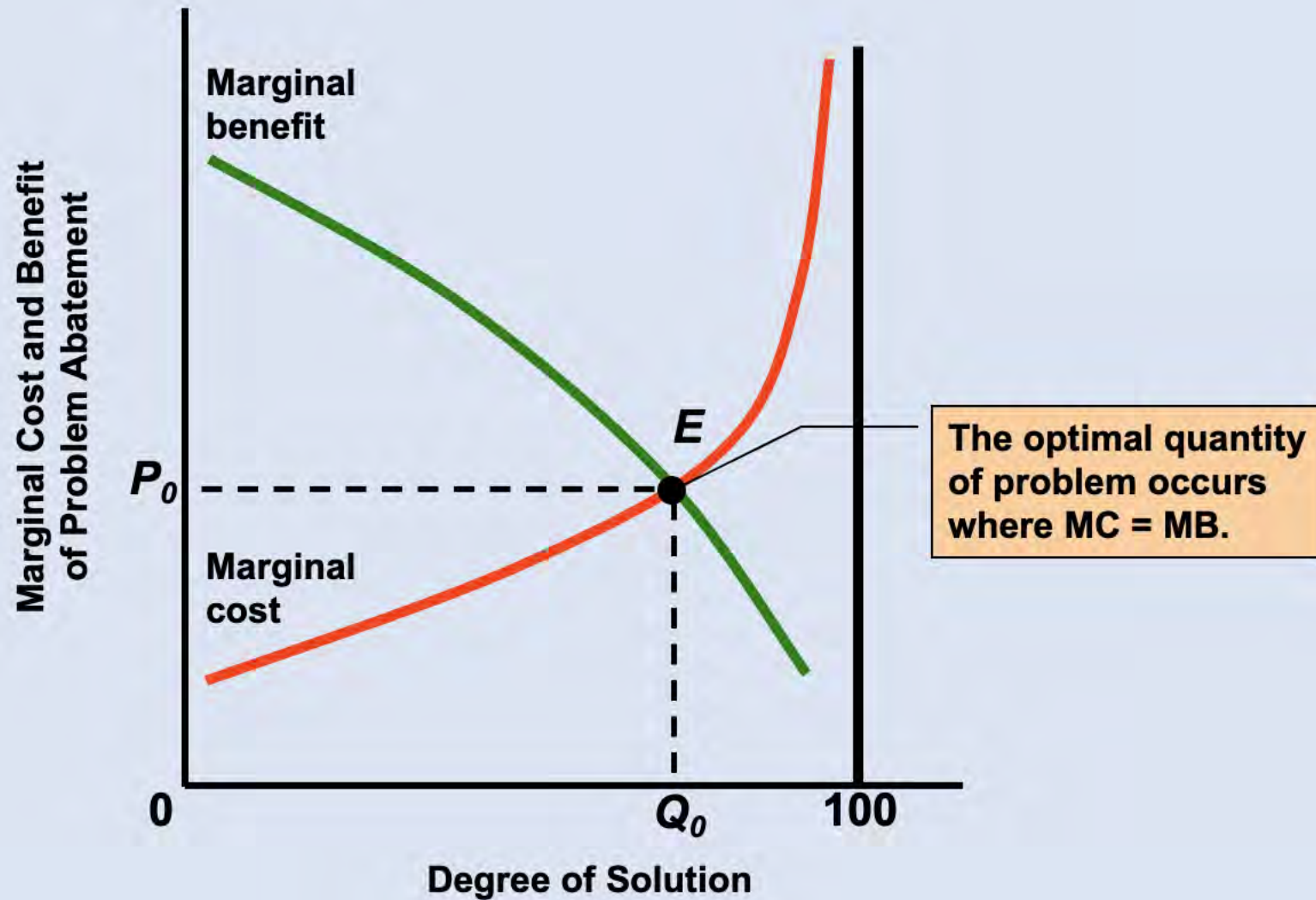
- E. Gramlich, *Benefit-Cost Analysis of Government Programs* (1981)

Benjamin Franklin Approach

“[M]y way is to **divide half a sheet of paper by a line into two columns; writing over the one Pro, and over the other Con** And, though the weight of reasons cannot be taken with the precision of algebraic quantities, yet **when each is thus considered, separately and comparatively, and the whole lies before me, I think I can judge better, and am less liable to make a rash step,** and in fact I have found great advantage from this kind of equation, in what may be called the ***moral or prudential algebra.***”



The “Optimal” Level of Problems



Optimality and “Right-Touch” Regulation

“The right amount of regulation ... balances the scale with the risk of harm – it achieves the desired result and no further. Too little is ineffective; too much is a waste and may impose unnecessary burdens or costs.”

Professional Standards Authority (2025)

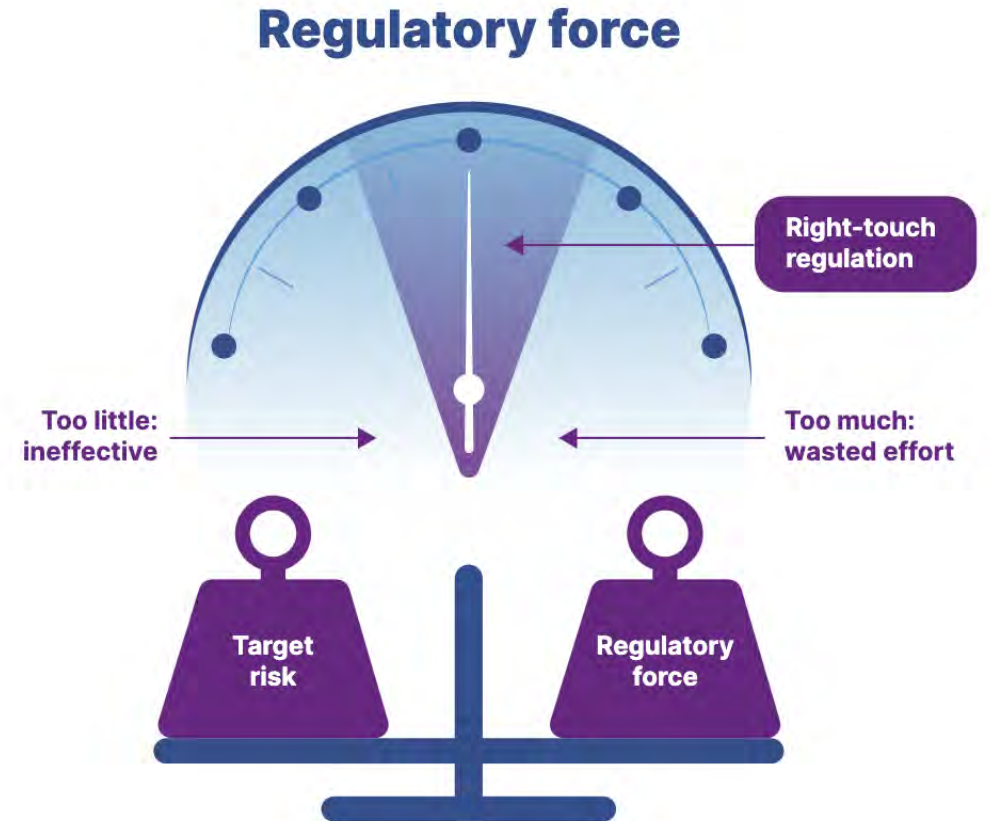


Figure 2: Balancing risk with regulatory force

Other criteria may matter, too....

- Acceptable risk
- Feasibility (acceptable costs)
- Administrative/paperwork costs
- Enforceability/administrability (to regulator)
- Innovation
- Competition
- Legal authority
- Political considerations?
- And more?

Risk and priority-setting



“Risk-based regulation means **targeting regulation and regulatory effort on things which pose the greatest risks to society or to regulatory objectives**. So risk-based regulation operates at two levels—in the design of regulatory systems and in their operationalization.

Designing regulation based on risk informs where to draw the regulatory perimeter—what falls within and what falls outside—and how to **calibrate regulatory requirements so that more onerous requirements are placed on those activities which are thought to pose the greatest risk to society, including the deployment of technologies.**”



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Risk-Based Regulatory Regimes

Melissa Bredbenner



The Sunday Spotlight

on regulatory leaders and thinkers

Julia Black

Professor of Law
London School of Economics and
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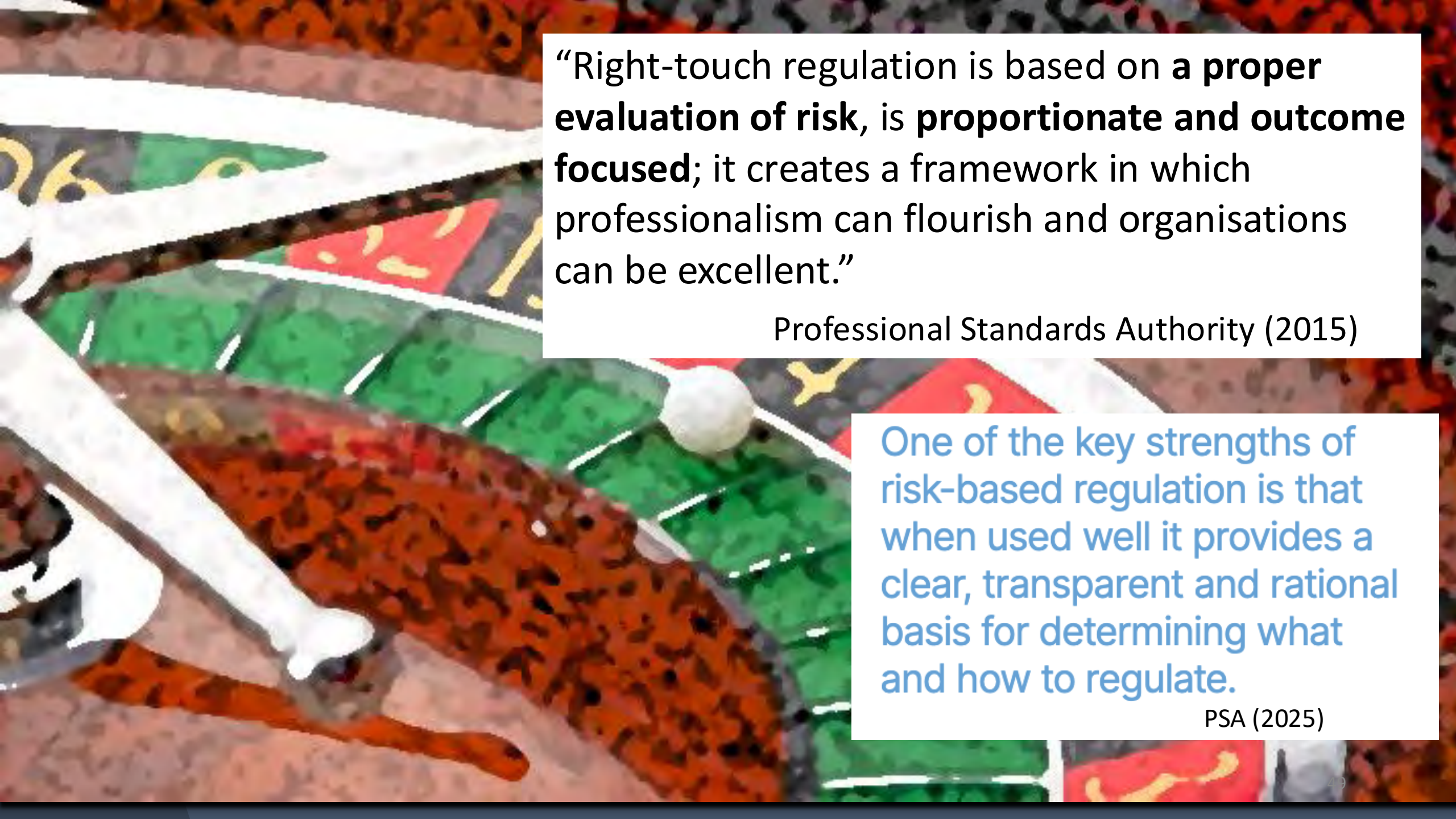
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Julia Black explains how regulatory regimes focused on risk can lead to greater coherence.

In a recent discussion with *The Regulatory Review*, [Julia Black](#), strategic director of innovation and professor of law at the [London School of Economics and Political Science \(LSE\)](#), offers insight into various kinds of regulatory regimes, including risk-based regimes. She also discusses the impact of third-party stakeholders on regulatory systems and discusses regulatory measures that aided jurisdictions during the COVID-19 pandemic.

In addition to teaching at LSE, Black serves as an external member of the Bank of England's [Prudential Regulation Committee](#) and its [Financial Markets Infrastructure Committee](#). She serves as a member of the U.K. Prime Minister's [Council for Science and Technology](#), and as a director of [Zinc](#), a social sciences-based incubator. Black also serves as president of the [British Academy](#), U.K.'s national academy for the social sciences.

From 2016 to 2017, she served as the Interim Director of LSE. She has also held a [British Academy/Leverhulme Trust Senior Research Fellowship](#), served as a visiting fellow at the [University of Sydney](#) and at [All Souls College](#), and served as the Sir Frank Holmes Visiting Professor in Public Policy at the [Victoria University of Wellington](#). In September, she will leave LSE to become head of [Nuffield College, Oxford](#).

A close-up photograph of a pool table. A white cue ball is positioned on the green felt, near a pool cue that is partially visible on the left. The pool table has a red and yellow striped border. The background is slightly blurred, showing more of the pool table and some greenery.

“Right-touch regulation is based on a **proper evaluation of risk**, is **proportionate and outcome focused**; it creates a framework in which professionalism can flourish and organisations can be excellent.”

Professional Standards Authority (2015)

One of the key strengths of risk-based regulation is that when used well it provides a clear, transparent and rational basis for determining what and how to regulate.

PSA (2025)

What is Risk?

RISK =

PROBABILITY x VALUE OF CONSEQUENCE

*In the regulatory context, the consequences are undesirable ones (e.g., insolvencies, accidents, cancers, medical errors, etc.)—that is, **hazards**. So, the value is **negative**, but the severity of the hazard can still be large or small.*

What is Uncertainty?

Risk = measurable/probabilistic

Uncertainty = unmeasurable or unknown

“‘[R]isk’ means in some cases a quantity susceptible of measurement... [A] measurable uncertainty, or ‘risk’ proper...is so far different from an unmeasurable one that it is not in effect an uncertainty at all. We shall accordingly restrict the term ‘uncertainty’ to cases of the non-quantitative type.”

Economist Frank Knight (1914)

Types of uncertainty



*“[T]here are **known knowns**; there are things we know we know. We also know there are **known unknowns**; that is to say we know there are some things we do not know. But there are also **unknown unknowns**—the ones we don't know we don't know.”*

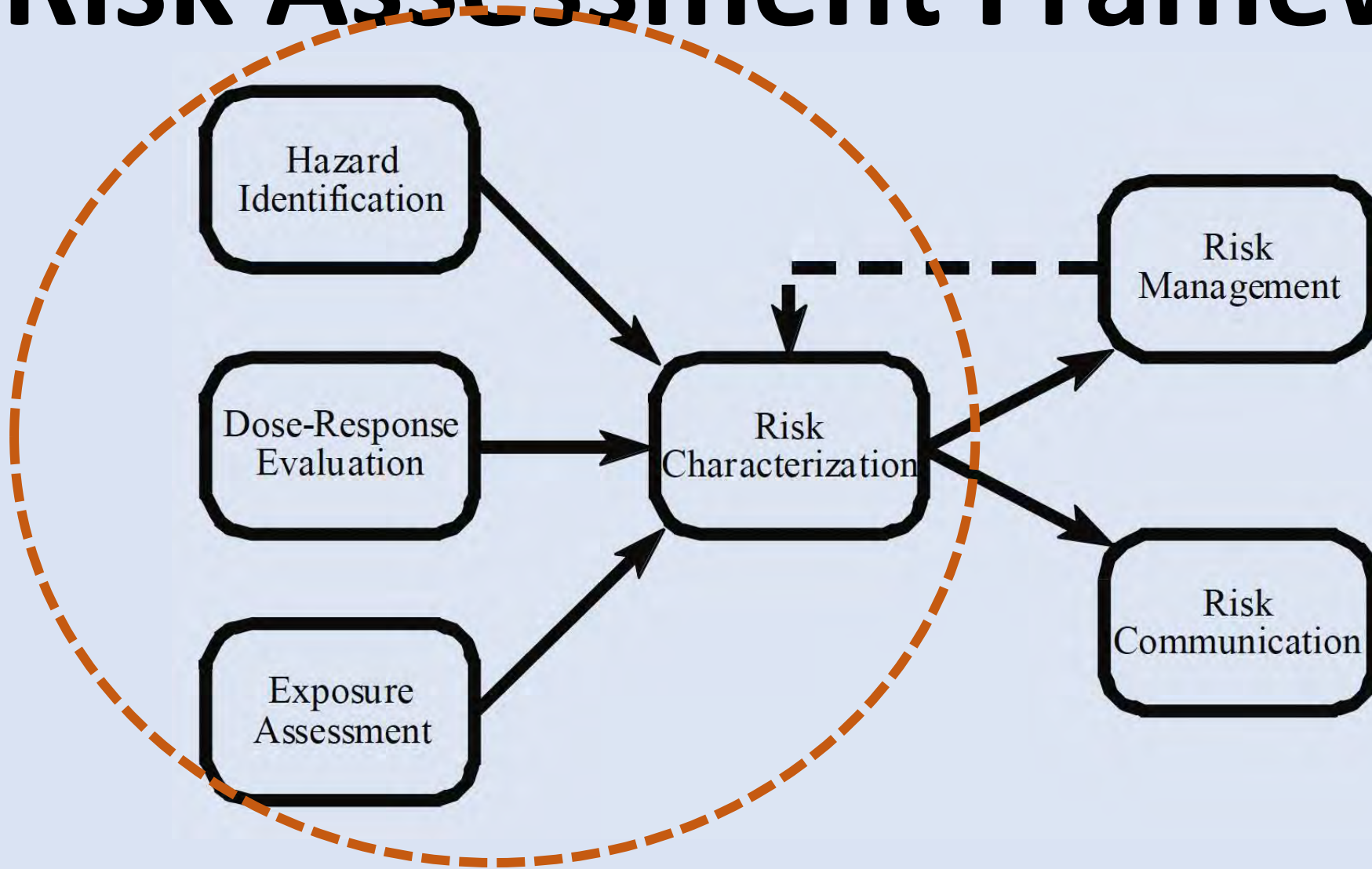
- Donald Rumsfeld

What is Risk Assessment?

“[A]ll available information and knowledge pertaining to the risk at hand ... organized in a highly systemic way, with the objectives of **characterizing the nature and size of the risk** and of **specifying the degree of scientific certainty** that can be attached to the various sets of data, models, and assumptions used to produce the risk estimates.”

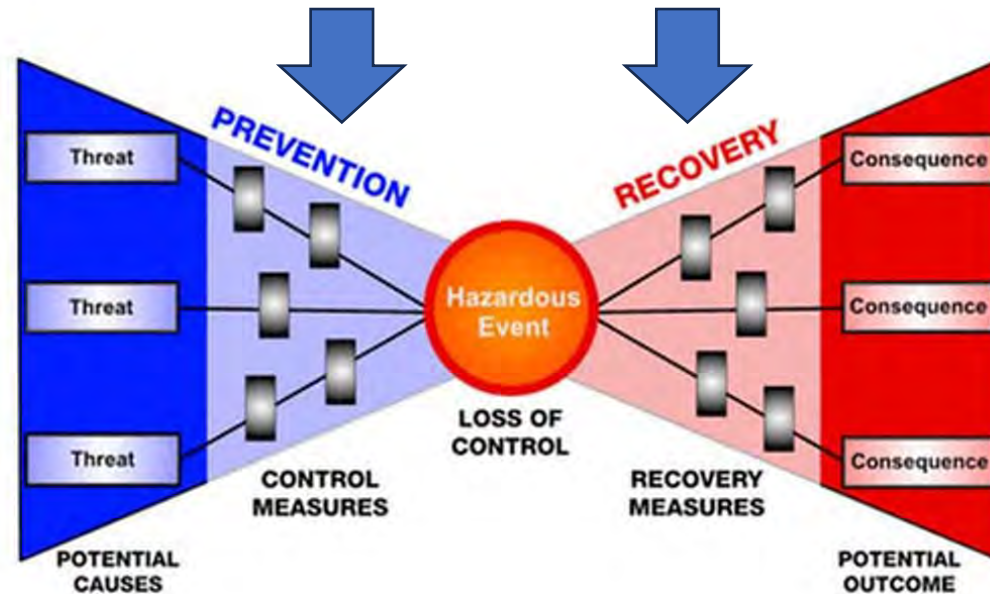
- Rodricks, *Risk Assessment, the Environment, and Public Health*, 102 *Envtl. Health Persp.* 258, 261 (1994).

Risk Assessment Framework



Risk Management Framework

Figure 2: A Generic Bowtie Diagram Illustrating a Causal System



Note: This diagram (from left-to-right) documents various hazards or threats and the variety of control measures (pre-event and post-event) that can limit the level of risk. Excerpted from Bowtie XP software documentation (CGE, 2015).

A close-up photograph of a dartboard. A white dart is embedded in the green ring, which is the triple ring. The dartboard has red and black segments with yellow numbers. The background is a textured, brownish surface.

What is a Risk-*Based* Regulator?

Key Questions to Consider

1. Risk to *whom/what*? Your organization? The public? Segments of the public (e.g., patients)?
2. *What* regulatory decisions should be “risk-based”? The making of rules? The enforcing of rules? Both?
3. What specific *values* should guide regulatory choices?

How does a “risk-based” regulator choose?

Option	Pr	Hazard	Benefits	Costs	Net Benefits
A	0.1	-100	10	20	-10
B	0.4	-80	32	30	2
C	0.5	-60	30	35	-5
D	0.6	-40	24	20	4

- Eliminate Largest Hazard

Eliminate Largest Risk

Avoid Excessive Costs (>25)

Avoid Unacceptable Risk (<-25)

“Do No Harm”

Maximize Net Benefits
- Option A

Option B

Option A or D

Option B or C

No Option? Or B or D?

Option D

“Once a risk has been evaluated a decision needs to be made about its tolerability. This can be a difficult moral exercise, and a decision will require clear and transparent justification.”

Professional Standards Authority (2025)



“Rather than providing a clear, principled guide for regulatory decision making, a call for *risk-based regulation* only necessitates making other choices which hold real policy implications but for which there are often few uncontested, determinative principles.”

- Coglianese & Sapir (2017)

Risk and Regulatory Calibration: WTO Compliance Review of the US Dolphin–Safe Tuna Labeling Regime

CARY COGLIANESE*

University of Pennsylvania Law School

ANDRÉ SAPIR**

Université Libre de Bruxelles (ECARES), Bruegel and CEPR

Abstract: In a series of recent disputes arising under the TBT Agreement, the Appellate Body has interpreted Article 2.1 to provide that discriminatory and trade-distortive regulation could be permissible if based upon a ‘legitimate regulatory distinction’. In its recent compliance decision in the *US–Tuna II* dispute, the AB reaffirmed its view that regulatory distinctions embedded in the US dolphin-safe tuna-labeling regime were not legitimate because they were not sufficiently calibrated to the risks to dolphins associated with different tuna fishing conditions. This paper analyzes the AB’s application of the notion of risk-based regulation in the *US–Tuna II* dispute and finds the AB’s reasoning lacking in coherence. Although risk analysis and calibration can in principle play useful roles in TBT cases, the AB needs to provide more explicit and careful guidance to WTO members and to panels to avoid the kind of ad hoc decision-making exhibited throughout the *US–Tuna II* dispute.

We live in a world filled with risk, and risk has come to dominate discourse over a wide range of domestic and international policy concerns (Beck, 1992; Jasanoff, 1999; Boyd, 2012). Risk obviously underlies multilateral environmental treaties related to trade,¹ and it finds expression in specific trade agreements on the use of risk assessment to guide domestic policymaking, such as the World Trade Organization (WTO) Agreement on Sanitary and Phytosanitary Measures (Howse, 2000). Risk has even found its way into general trade law principles. Article 2.2 of the WTO Agreement on Technical Barriers to Trade (TBT), for

* Email: cary_coglianese@law.upenn.edu

** Email: andre.sapir@ulb.ac.be

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¹ An example would be the Basel Convention on transboundary shipments of hazardous wastes.

Now, let's look back!



Measurement serves many purposes.

The most important of these is...

to learn.



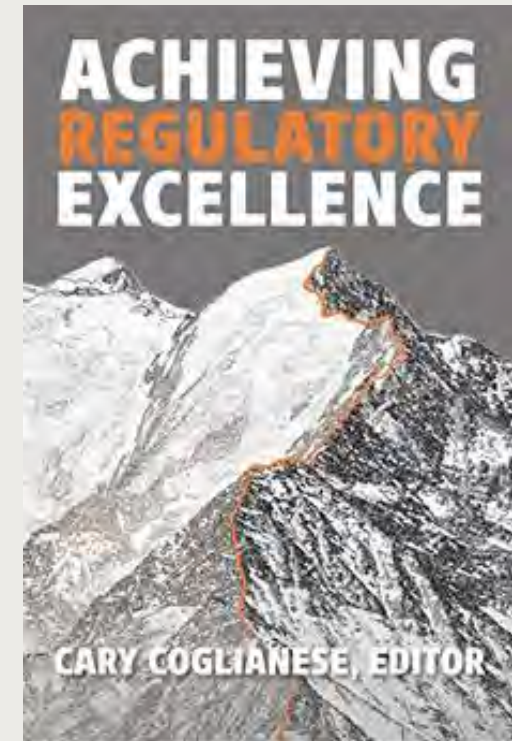
THE GOOD THE BAD AND THE UGLY

Image credit: SilverScreen/Alamy

“Do not attach high-powered incentives to goals you can only measure imperfectly...

Build ‘learning forums.’”

Moynihan (2017)



Choose metrics that are ...

- **Relevant**
 - Related
 - Tight
- **Reliable**
 - Accurate
 - Resistant
- **Realistic**
 - Available
 - Intelligible



*Measure with excellence too:
**utmost integrity,
stellar competence,
empathic engagement....***

Methods of Measurement

1. Actions (bean-counting)
2. Outcomes (stock-taking)
3. Action → Outcomes (causation)

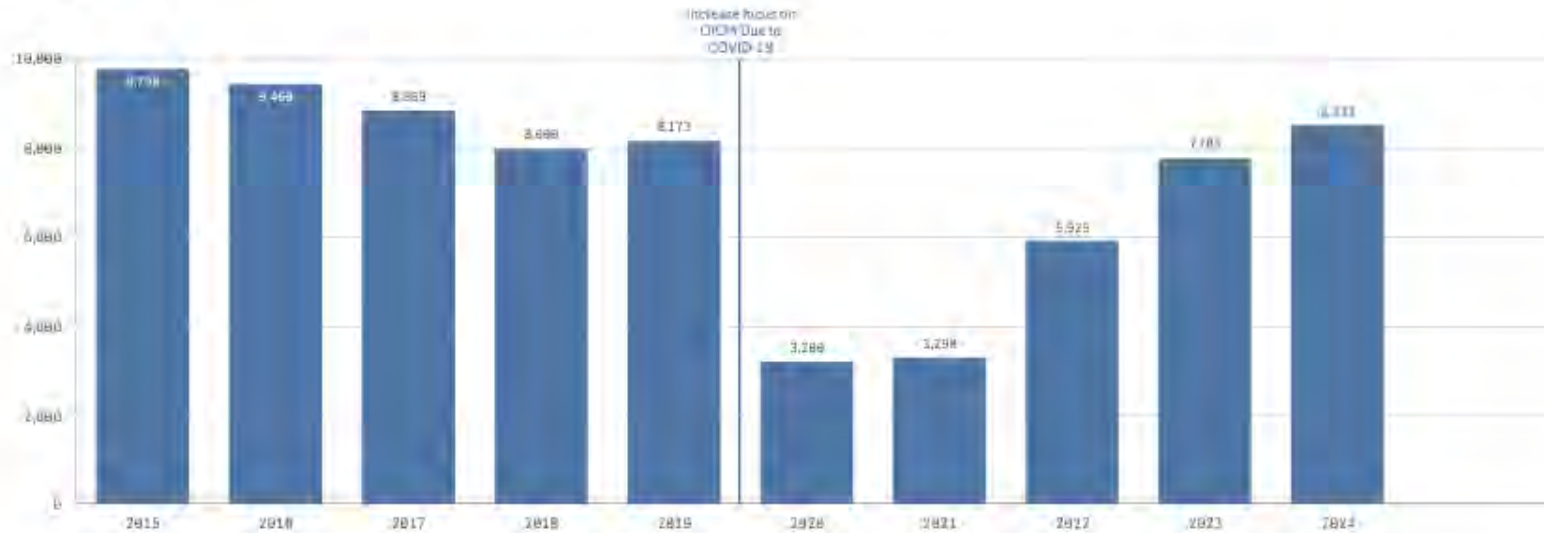
Note: Avoid linking measurement to organizational incentives. Remember, the most important reason for measurement is to learn!

Action Measurement

Federal Inspections Conducted by EPA FY 2015 – FY 2024



Count of Inspections



Highlights:

- In FY 2024, EPA performed over 8,500 inspections, which is over a 9% increase compared to FY 2023.
- The highest number of inspections over the last seven years.

Footnotes:

1. An inspection is performed on-site at a regulated facility or activity.

Stop Green

Show Table

Export Data

Data Source: Integrated Compliance Information System (ICIS), RCRA Info (for RCRA HW), manual (for SDWA UIC)
Data as of: November 13, 2024

U.S. Environmental Protection Agency

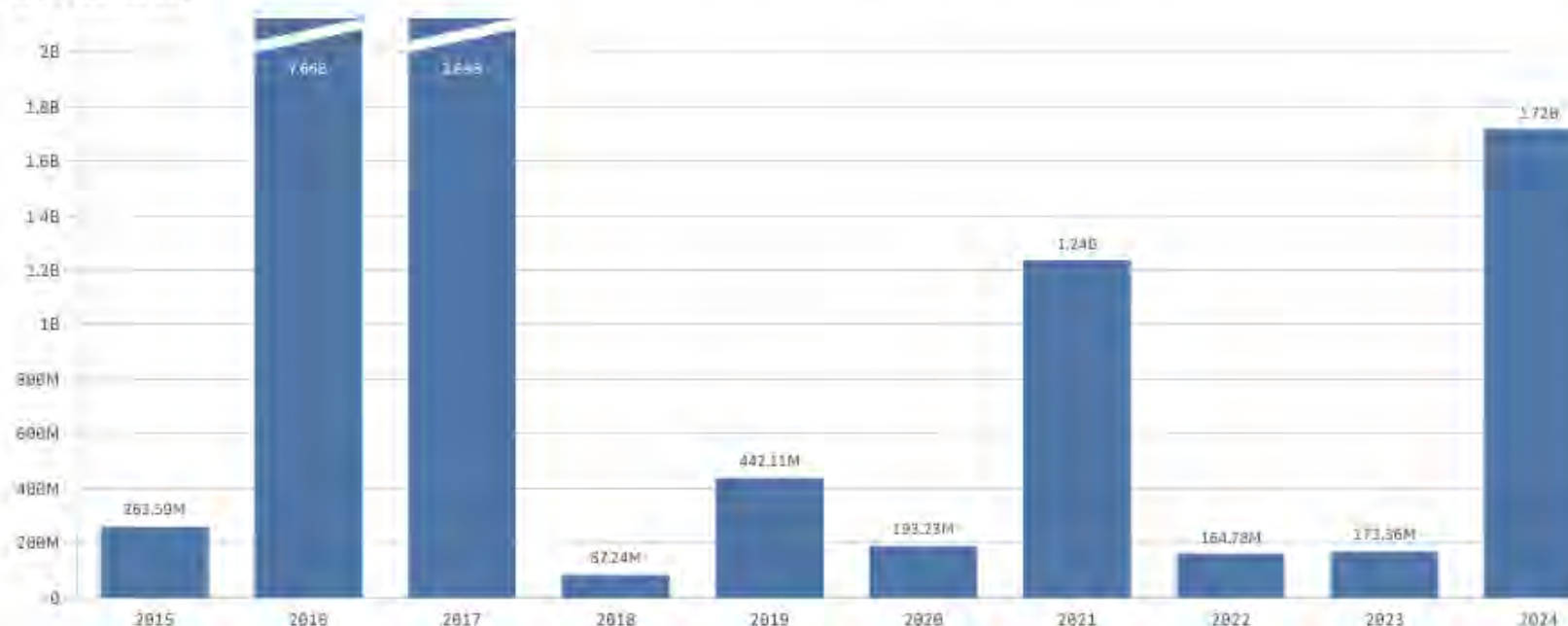
Top of Page

Action Measurement

Administrative and Civil Judicial Penalties Assessed FY 2015 – FY 2024



In FY 2024 Dollars



- In FY 2024, EPA assessed over \$1.7B in federal administrative and civil judicial penalties.
- The Cummins Inc. Vehicle Emission Control Violations Settlement accounted for 86% of the total FY 2024 penalty amount. The \$1.48 billion penalty was the largest ever assessed in a Clean Air Act case.

Footnotes:

1. The rate of inflation/deflation is determined by the U.S. Department of Labor Consumer Price Index for All Urban Consumers.
2. Dollar figures referenced in the bullets are not adjusted to reflect inflation/deflation.

Data Source: Integrated Compliance Information System (ICIS)

Data as of: November 13, 2024

U.S. Environmental Protection Agency

View Graph

Show Table

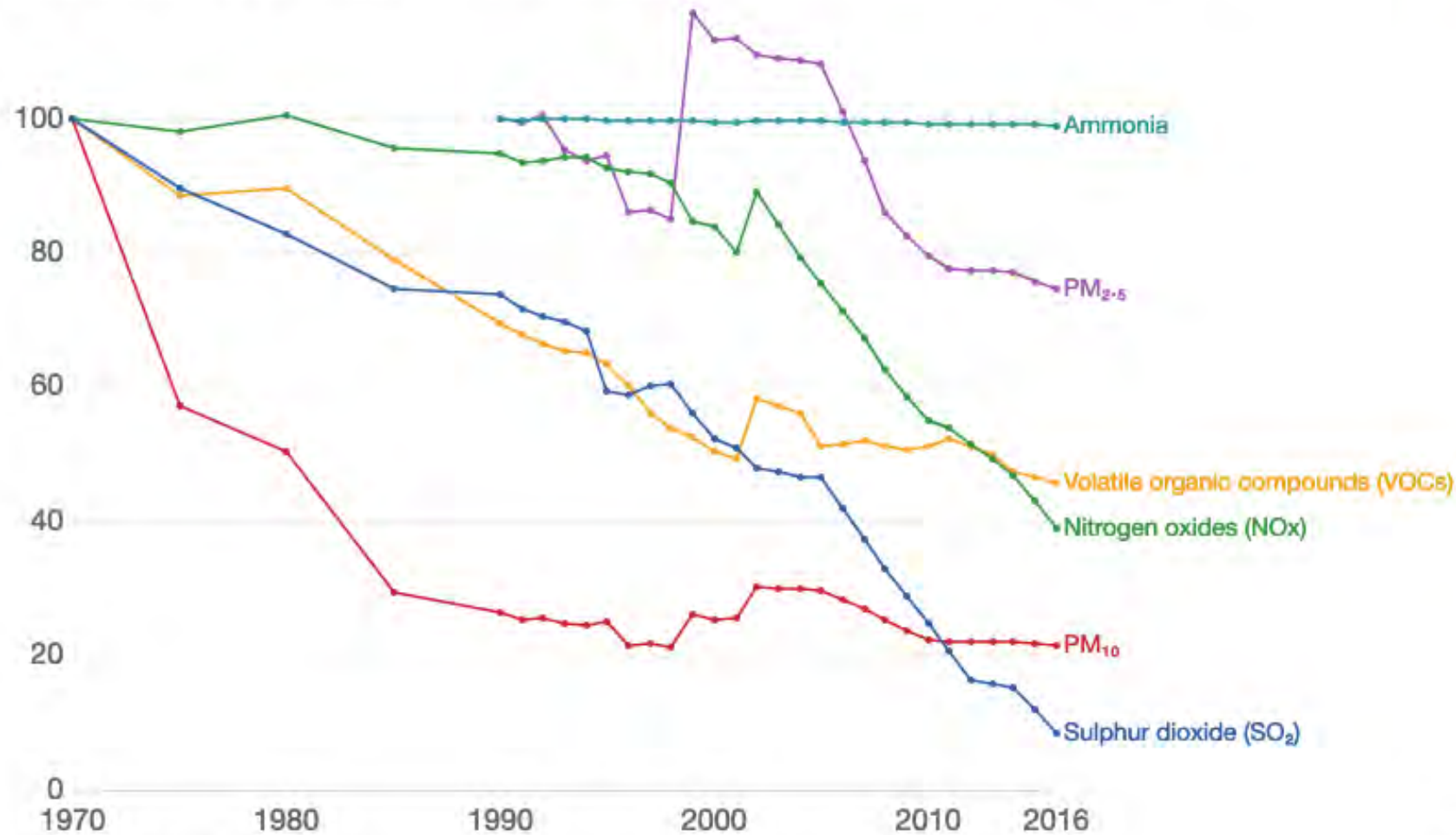
Export Data

Outcomes Measurement

Emissions of air pollutants, United States

Our World
in Data

Annual emissions of various air pollutants, indexed to emission levels in the first year of data. Values in 1970 or 1990 are normalised to 100; values below 100 therefore indicate a decline in emissions. Volatile organic compounds (VOCs) do not include methane emissions.



Source: UK DEFRA; US EPA

CC BY

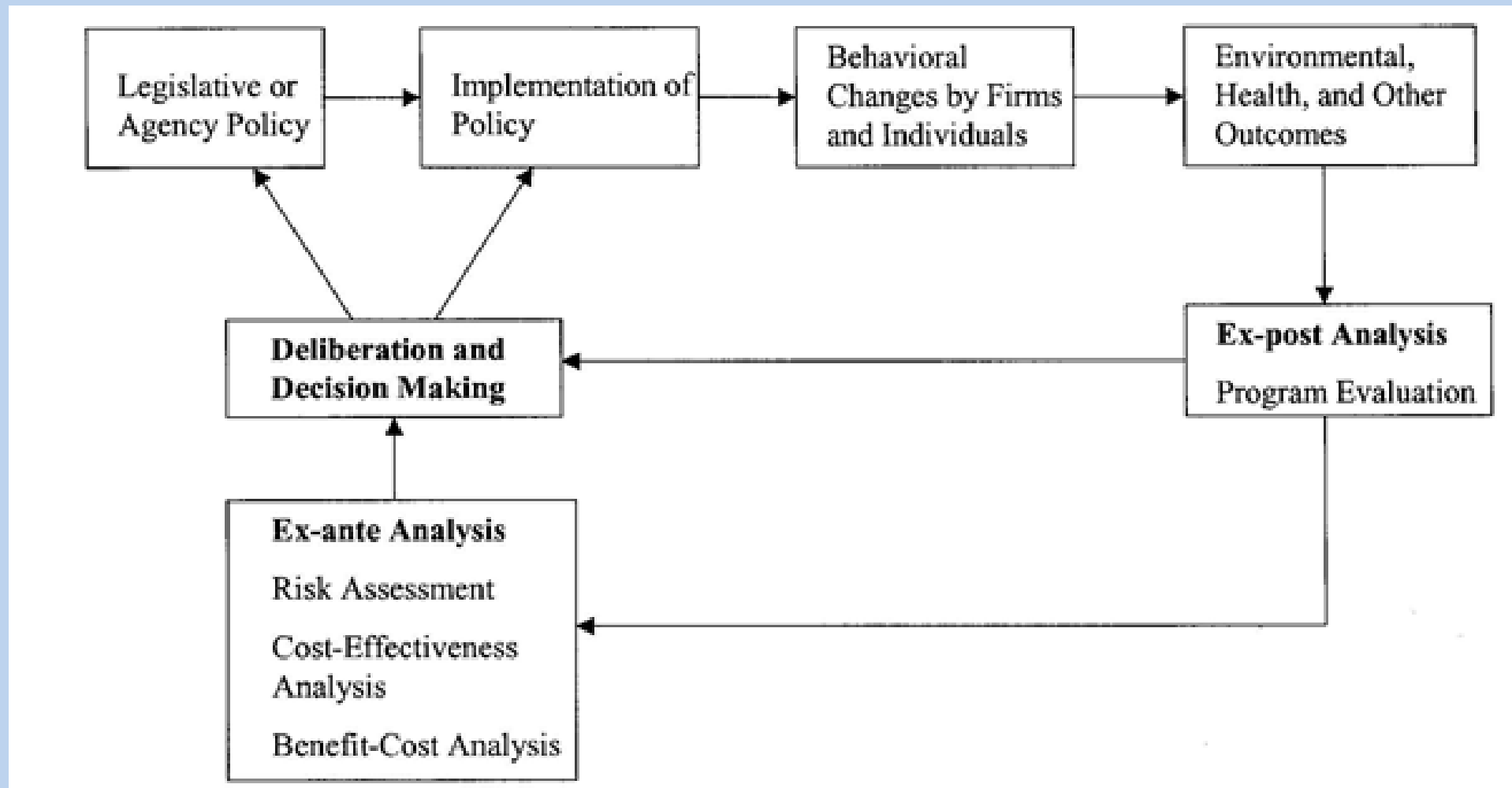
Why Causal Attribution is Key

“Non-attributional research can indeed be helpful in monitoring whether problems are getting better or worse. However, non-attributional evaluations cannot explain ***why*** problems are getting better or worse. ... ***Only attributional evaluation can answer the fundamental question of whether and how well regulation is working.***”

Basic Strategy for Causal Attribution

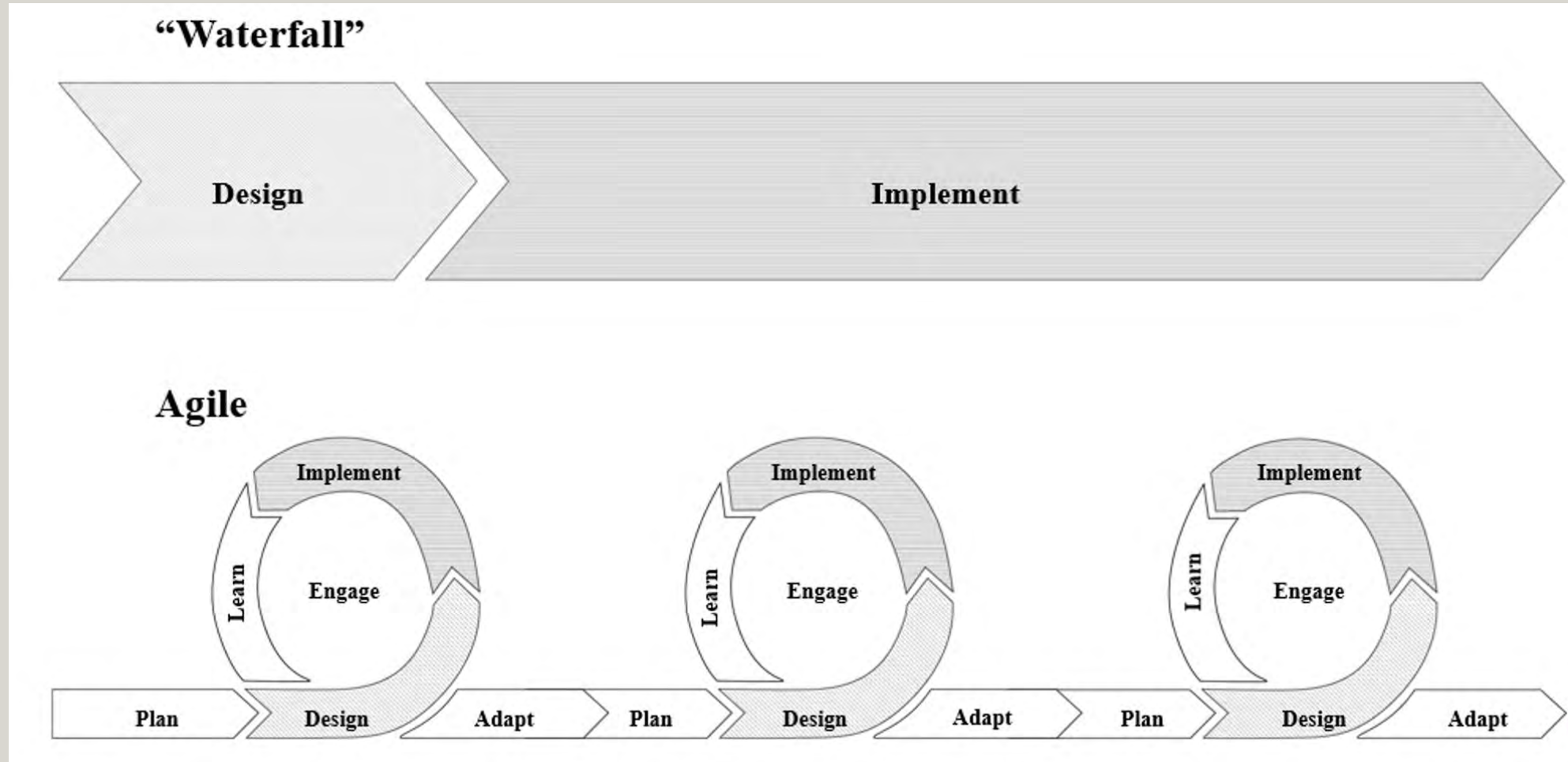
- Measure against the “**counterfactual**” (i.e., world without the regulation or intervention being evaluated)
- Counterfactual must be **estimated** (except in laboratory experiments, it is never observed)
- Research designs/strategies to estimate the counterfactual **exploit variation** in treatment (but seek to control for variation in everything else)

Attributional Evaluations (Ex Post) Can Produce More Informed Regulatory Decisions (Ex Ante)



Source: Coglianese & Benneer (2005)

Make Measurement Ongoing



Source: Kariv-Tietelbaum & Coglianese (2023)

Regulation 2030 First Steps of A Journey

“Regulation is no different from any other aspect of today’s society: It cannot remain dormant in light of the rapid pace of changing data systems, information security and use, and predictive analytics. All these technologies are important to regulators and offer additional areas for scientific exploration”

Journal of Nursing Regulation (2017)

“Regulation
is a verb.”

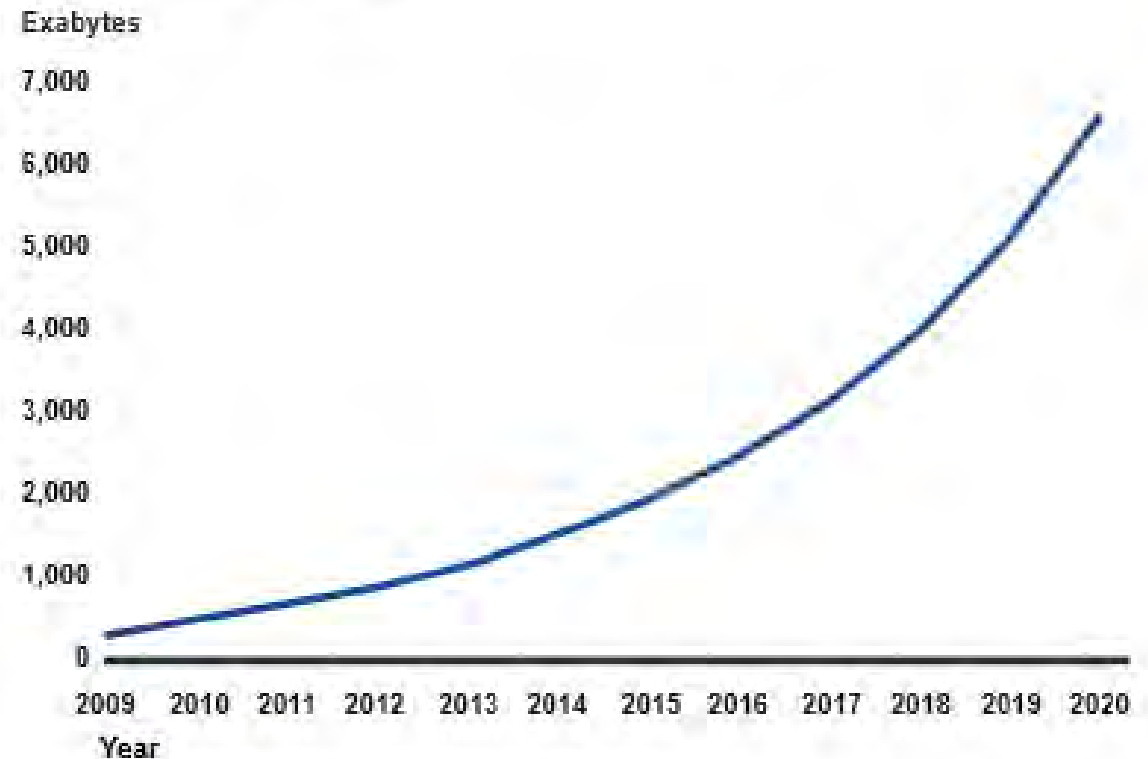
Coglianesse (2024)

Expanding growth in data

Data volume is estimated “to double about every 3 years.”

US GAO (2014)

Figure 20: Data Created, Replicated, or Consumed in the United States



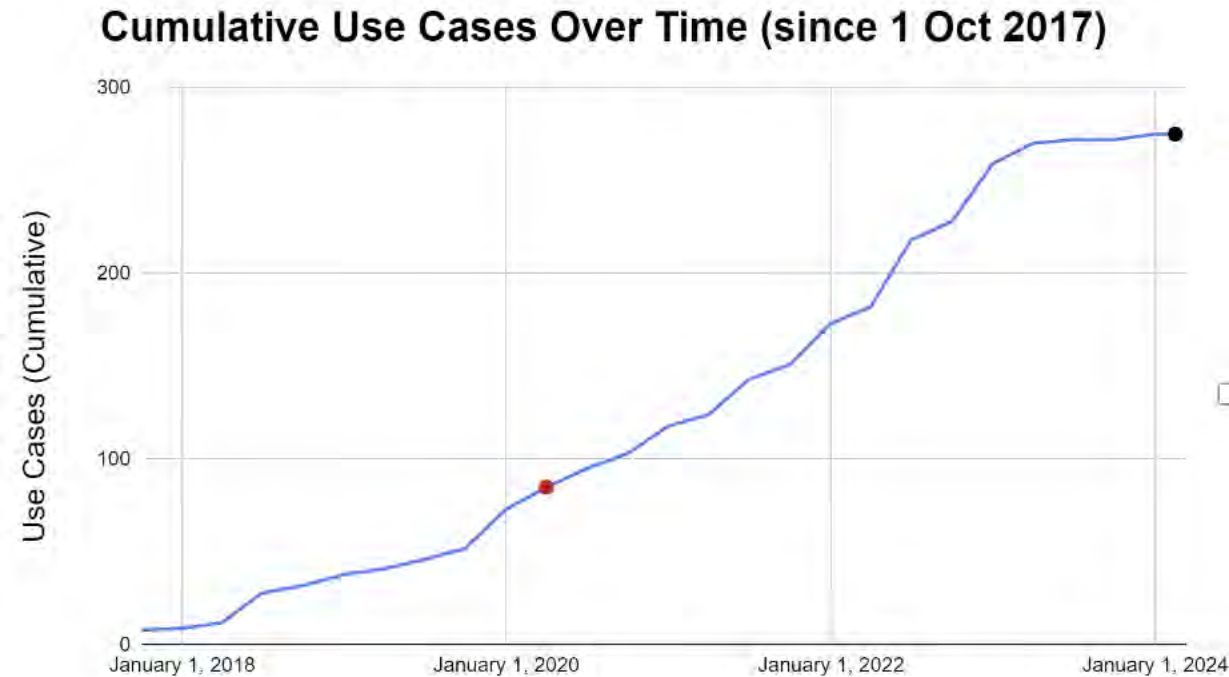
Source: GAO analysis of EMC – IDC Digital Universe Study.

US GAO (2014)

Expanding use of AI by government agencies

In 11 federal agencies, “the number of reported AI use cases nearly doubled from 571 in 2023 to 1,110 in 2024. Generative AI use cases increased nearly nine-fold from 32 in 2023 to 282 in 2024.”

U.S. GAO (2025)



Coglianesse et al. (2024)

Regulatory uses for artificial intelligence

Common regulatory problem: vastly more regulated individuals and entities than regulators can oversee.

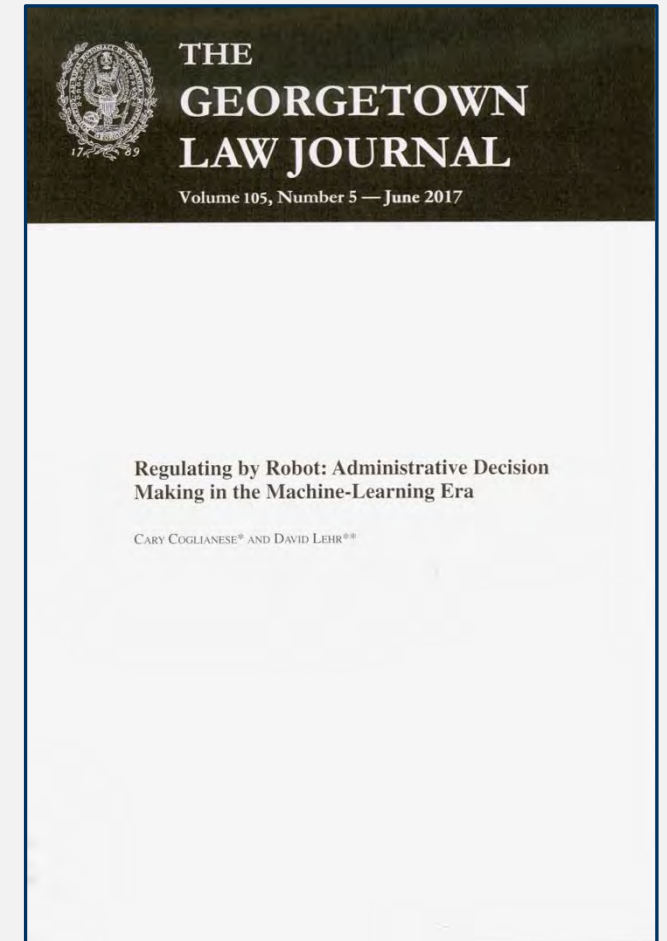
- Who to investigate?
- Who to prioritize?
- Who to educate?



So yes, excellence requires data and technology ...

“[T]he increased speed and complexity of economic activity in the machine-learning era surely demands that government agencies keep pace”

Coglianese & Lehr (2017)



But most important of all.... regulatory excellence is ‘people excellence’

“Only if the people working in a regulatory organization are committed to doing their utmost to deliver public value, and to learning and to improving their ability to deliver value in an environment that requires respectful engagement with others, can a regulator expect to achieve true excellence.”

Coglianesse (2015)



Cary Coglianese
Edward B. Shils Professor of Law
Professor of Political Science
Director, Penn Program on Regulation
University of Pennsylvania

www.PennReg.org
www.TheRegReview.org
www.BestInClassRegulator.org
www.CaryCoglianese.net



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