Past Event: 2026 NCSBN Annual Meeting – Regulating with Precision: Data-Driven, Risk-Informed, Right-Touch Video Transcript

Event
2026 NCSBN Annual Meeting

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Presenter
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- [Cary] Good morning, everyone. Really delighted to be here in Chicago with such an important and vital organization for our nation and its public health. And I want to just say personally how apt it is for me to be here in Chicago with such an organization as yours because I was born here in a public hospital in the city of Chicago and owe, in some sense then my whole existence to the quality of healthcare delivery and nursing care that I and my mother received when I was here all those so many years ago.

So it's a pleasure to be with you this morning and to talk about priority setting, problem-solving, regulatory excellence. I've been asked to spend the next 90 minutes or so talking about work that we've been doing at the Penn Program on Regulation that cuts across many different areas of regulation but which also speaks to regulation in any setting and particularly in the healthcare setting.

I hope to do three big things with my remarks this morning. First, share with you thoughts about regulatory excellence and how to either maintain or pursue regulatory excellence in all that you do.

That's point number one. Then I will also focus on problem-solving and priority setting in making regulatory decisions either about the type of rules that are in place or the implementation or enforcement or carrying out of those rules. So that'll be number two.

And then I want to step back. The third thing is look at some thoughts and share with you some thoughts about metrics and measurement in the world of regulation and what you do, how to be looking back and assessing how well you're doing.

The bottom line is I'm going to talk about what often comes under the banner of, at times, data-driven regulation or risk-based regulation or right-touch regulation. But I guess my main message is that those catchphrases are just that.

They only scratch the surface of what an excellent regulator needs to be doing and thinking. It's important in what I say here today for you, I hope, to think about these ideas and apply them in your setting to fill in the details.

I'll offer some general models and frameworks, but these general models and frameworks only actually work when you take them home, internalize them, think them through. It's important to choose values and to pursue vigilance, two Vs here that will be, I think, a theme undergirding my remarks: values and vigilance.

A lot today is talked about with respect to technology and data, and those are always important. They're increasingly important in today's world and today's world of regulators in any field. But ultimately, it's your leadership, the values and vigilance that you and your teams that you lead, that matter the most.

Regulatory excellence doesn't come with any easy answers. It also, though, depends ultimately on people excellence. So let me just level set with some ideas that I think will be widely understood in this context. Why seek excellence in regulatory priority setting and problem-solving?

What we're really here to talk about today. And about 20 years ago, Atul Gawande, a surgeon, wrote about excellence in the healthcare setting and answered the question there: why excellence?

Why pursue excellence? Simply because lives are on the line. And he wrote that healthcare professionals face daunting expectations. They're operating in areas where the steps are often uncertain, where knowledge is expanding vastly, and yet professionals are expected to act with swiftness and consistency and to do work humanely and with gentleness and concern.

And when I published a book some years ago called "Achieving Regulatory Excellence," I wrote that Gawande could just as well have been writing about regulators, and he certainly could have been writing about regulators in the healthcare field. Now, one of the things about regulation and success in regulation that differs from perhaps success in other domains of life is that success in regulation looks something like this.

Now, what do I mean by that? I don't mean that it's a blank slate, that there is no such thing as regulatory success. Rather, what I mean is that regulatory success is hard to see. It's relatively invisible.

It's life going on as it should be. It's patients getting the kind of care that they're supposed to get. By contrast, failures of regulation can asymmetrically be visible and get a press attention, get attention in the courts, and so forth.

And this is a challenge, a challenge for regulatory excellence. In the field of medical professionals, across all medical professions, the nursing community should be very proud that you rank at the top of public surveys about the honesty and ethical standards of those who operate in these fields, with 75% of the public seeing nurses as honest and ethical, and rate them very highly in those qualities.

But as you probably are aware, public attitudes toward medical professionals across the board have declined over the years. In 2018, that 75% rating was actually at 84% for nurses. And, of course, corresponding declines in other domains.

So as you go about your work, you're operating in a public sphere that is less trustful, less supportive overall of experts, and of even medical professionals, and even of nurses. You're also operating in a

highly complex environment where, yes, the goal at the center of everything that you do is quality healthcare delivery, but licensing boards are only one of many, many factors that are affecting that.

And this is one of the reasons why regulatory excellence can be so challenging. Regulatory excellence, I like to remind people, is a lot like climbing a very steep mountain and walking along the knife's edge of a mountain ridge.

In fact, the word that mountaineers have for that knife's edge is called arete. It's an ancient Greek term, and it translates to modern English as excellence. And it seems apt to think about that as a metaphor for what regulators are doing because so much of what you're doing, again, lives being on the line, often is right at that knife's edge where one false step might create some kind of lapse in that goal of healthcare delivery.

And where you're bound up, where you're bound up with others on your team, but also those within your profession. When we ask about what makes for an excellent regulator, it differs from excellence in so many other domains.

Sometimes I ask people to think about, well, what makes for excellence in art or music? And it's different. Even someone who's doing such challenging work in the musical arts, such as, let's say, Yo-Yo Ma, has his cello there with him and has a good degree of control over that cello.

Yes, tremendous amount of talent goes into it, but what makes for an excellent regulator is so much even more challenging because your proverbial cello is moving around. Your success, I like to say, is interdependent on others' success, whether it's healthcare facilities that might be overseeing their nursing staffs or those nursing professionals individually themselves.

And again, one false step can make the real difference. Now, I've been working in the field of regulation for over 30 years, and a lot of what I have to say here really draws on all that we've been learning at the Penn Program on Regulation and all that I've been learning throughout my career.

About 10 years ago, we did a project for a Canadian regulator, an energy regulator to be sure, that was aimed at trying to distill key lessons about regulatory excellence. And the aim of the project was certainly to help that particular regulator, but also broad enough to encompass the work of other regulators.

In fact, a review of our final report from this project, which actually generated over 25 different papers and other reports, but the final report was reviewed in the "Journal of Nursing Regulation."

And it was described there as characterizing principles that were "universal" and applicable to all walks of regulated life, professions, or industries. In that project, we sought, first of all, to make some headway on thinking about, well, what is it that counts as regulatory excellence?

And going back to the word arete, we looked back to some of our classic readings and noted that Socrates once said that when he was looking after one virtue, he actually found many. And that characterizes what we found in our efforts to see what others thought regulatory excellence would be.

We convened numerous multi-stakeholder dialogues. We interviewed folks in regulated fields. We looked at regulators' reports.

We interviewed regulators from around the world. And we found many. If one looks at just the right-touch regulation principles, for example, which I think some of you, maybe all of you, are familiar with, you'll see that there are six main virtues or principles of right-touch regulation.

Regulation that's right-touch should be proportionate, consistent, targeted, transparent, accountable, and agile. And we found many, many other sets of principles that described a high-quality regulator when we talked with people from around the world.

And this is not a chart that I'm expecting anybody to be able to read. This is just an appendix from actually an interim report we delivered. The final report is an even more expanded list that I couldn't fit onto one slide. In some respects, it's not an exaggeration to say that in many people's minds, when you ask them what is an excellent regulator, they will give you almost any positive attribute or any positive adjective that describes an excellent regulator, except maybe those related to physical beauty or to smell.

We didn't encounter any of those, but almost anything. Now, that itself is telling, isn't it, that there's an expectation that you be all things to everyone, that you get the right touch, that you do the right thing.

And that's challenging to manage any organization. And what I've been speaking about to groups around the world and regulators around the world is how to manage an organization toward regulatory excellence.

And it's hard to do that when you've got to be everything to everyone. So what we try to do as analysts and scientists, social scientists, and policy analysts is try to get some leverage on what we were hearing.

So one thing we first did is take all of these attributes and try to group them into a smaller subset. We did about two dozen or so, a smaller subset of attributes, and then classify how frequently they emerged. And this is what came out of that particular analytical exercise.

It's a word map that shows how these different categories into which we put things, the larger the word, the more frequently it arose. Obviously, you can see what, for many, many people, is top of mind to all that you're doing. And I guess that makes sense in today's world of the internet, social media, in a way that probably didn't 30 years ago or more, when I started in the field, transparency being so vital.

By the way, even this is hard to manage around with that many different qualities. So we took things a step further and began to realize throughout our dialogues that when it really came down to it, there were three core attributes that were interconnected in regulatory excellence, so interconnected that I call them atoms of excellence that form a molecule called RegX for regulatory excellence.

What were these? Well, the utmost integrity was really important. And that's not just the absence of corruption, but it's so much more a commitment to public service and public ethos and spirit. And I think most people in the regulated world I've talked to understand that that's a good precondition for any regulator that seeks to be excellent at what they do.

And stellar competence is also important: being able to do the kinds of problem-solving, priority setting, interventions, good quality investigations, making fair judgments, preventing risks from arising.

That stellar competence, I think everybody also has long recognized, is crucial. The third quality, empathic engagement, I think is one that is a relative newcomer. Again, maybe because of the advent of the internet and social media, people are starting to realize in the regulatory space that it's not like it was

30 years ago where regulators and regulated entities could be in more closed-knit worlds that may be out of the limelight, but empathic engagement is really important.

And by empathic engagement, that's not just with the broader public that might be now connected on the internet. It's empathic engagement not just to the beneficiaries, the patients, and so forth, of the work that you're doing, but it's also empathic engagement with the regulated community as well.

Now, we distilled that to three main atoms, but within each atom we identified three core tenets of each that relate to then nine tenets of regulatory excellence. I'm going to come back to these in a bit, and I won't go through all of them.

These are all outlined in our final report, which you can download from our website at the Penn Program on Regulation. We have a website on regulatory excellence and have all of our reports, and the final one too, there. But let me just say a little bit more about empathic engagement.

It does mean a little even-handedness. It means listening, and it means responding, but listening and responding doesn't necessarily mean always doing exactly what everybody wants you to do. In fact, often that's impossible for regulators. That's the knife's edge that you're on where the winds are blowing sometimes in either direction.

So with this as just a grounding, a brief overview of regulatory excellence and how you might walk away today and think about it, what does it mean to achieve regulatory excellence? How to get up that path and continue up that path toward the summit of regulatory excellence?

Well, let me shift and think about excellence just in medical care with a model of performance that was published back in the early 1990s, but I hope resonates with a standard kind of treatment model in the healthcare field that's a means-and-ends relationship.

This diagram, and I'm not here to defend exactly how it's all mapped out, but appeared in a book that the Harvard University Press published by a decision analyst, Ralph Keeney, some years ago, in which on the right he articulates fundamental objectives for cancer treatment, which would be not increasing the likelihood of death but reducing it, reducing any limitations on activities and personal costs and inconvenience, pain and suffering, and so forth.

These are the fundamental objectives in the medical world to anyone working with cancer patients. And then how to achieve that is through some kind of means, means through high-quality healthcare, through treatments that are effective, that have relatively few or benign side effects, or at least minimal, right?

So means and ends in medical care, I think, translates over to a means and ends model of regulatory performance. At the far end of this are the substantive outcomes that a regulator is trying to obtain. That quality healthcare delivery, that reduction in hospital-acquired infections, might be a substantive outcome.

The proper administration of prescription medications, substantive outcomes for a healthcare regulator. Now, along the way, there's lots of intermediate outcomes, making sure that professionals are trained and committed to delivering that healthcare quality.

That behavior among those that are regulated is really crucial. As you walk back to the left, it's really on the left side of this model that regulators and what you do matters to what is on the right side.

And by the way, down at the bottom on that right side, I include perceptual outcomes because it's not just that, in fact, there are good healthcare outcomes, but also there's a perception, remember, with those public opinion surveys, that people trust in the medical system and in the nursing profession.

But it's this left side, this is what you do. It's the people in your organization at the very far left, it's you and your teams and how that internal management is operating.

And then it's what you do, the priority setting, problem-solving, and the engagement with others. Those are your tools, your actions that affect what's on the right, excuse me here. What's on the left affects what's on the right.

And by the way, what you're, I think, like any other regulator, trying to do is shape the behavior of those who are subject to your regulatory oversight, the professionals that are licensed by your boards, so that they can then achieve those ultimate substantive outcomes.

This is what I call the bridge. Compliance with regulations is the bridge to regulatory excellence. Your actions shaping the behavior of those that are regulated to then create a bridge to that better outcomes.

Another way of looking at it is to say you can have all the rules that are written out, like this rule that I actually snapped this picture of in a hospital, a rule that says this door must be closed at all times. The words are written. But what, of course, did I see but a little brick propping open one of those doors?

And I think this is a metaphor, right? And we probably all can recognize that there can be rules that are written down, procedures that are put in place, but if nobody follows them, right, what good are they? Right? So compliance comes, and it is really that bridge between making sure that what's supposed to happen actually does happen.

And if the rules are written in a way that does protect the public, if the rule really is important that these doors be closed, then it really matters that they, in fact, be closed. Now, one of the principal ways that regulators have to shape compliance is through enforcement. And maybe some of you have heard this aphorism from a regulator in the New Deal era who said that, or at least is often quoted as having said that 20% of the regulated population will automatically comply with any regulation, 5% are going to attempt to evade it, and then 75% will comply or not, depending on what happens with the 5%.

Now, I put this up here because this is such a widespread quote about regulatory compliance and the relationship between enforcement and compliance, but it's not based upon any empirical studies or realities.

In fact, if you are really interested, I wrote a paper recently in which I went back to the source of this quote and explained how even that particular quote and the percentages in it don't match what was in the original source by Chester Bowles. But it does raise the question: why do people and regulated firms, which are just simply organizations made up of people, why do they comply?

Why do they comply? And I think the quote certainly captures that for many people, there is an intrinsic tendency to follow orders. And we know this from a number of psychological and sociological studies. There was a study in the last 10 years done, in which research subjects were brought in under the guise of doing something else, and the researcher said, "Before we start, I just need to check your cell phone. Can you give it to me? And I'll be right back with it."

And many people just handed over their cell phones and let that person leave the room with it. A lot of people are hardwired to follow. The famous Milgram experiments, which maybe many of you have heard about from the middle of the last century, where some research subjects were asked to deliver what they thought were electrical shocks.

They really weren't, but they ended up just by being told by the experimenter that the experiment must go on, increasingly delivering what they thought was a higher and higher electrical surge. All to the point where the person in the other room, not visible to them, who was supposedly connected to the wires, would make audible moans and shrieks even about the electrical shocks.

They just kept delivering them. So there is an intrinsic tendency that many people have to follow orders. And that's certainly there. But do we depend on that as regulators? Can we depend on that? Well, no, no, I think there's other reasons why people follow the law.

A good bit of research as of late shows that if people feel that the law or regulations are legitimate, and that's why that transparency and that engagement is so important, because when they see it's legitimate, they're more likely to follow.

And Tom Tyler, a social psychologist at Yale, has done a lot of work on procedural justice and finds that that relates to compliance. A really terrific randomized controlled trial done in Vietnam where some small businesses in some parts of Vietnam were given voice and an opportunity to be heard before regulations were imposed upon them, and others weren't.

Those regions that had the participation, they complied more. So legitimacy is also important. But then deterrence matters too. Both specific, targeted, punitive threats, but also general threats. So that, like Chester Bowles was saying, people don't feel like suckers.

They know that if there is an active regulator out there, that there's a level set of fairness that those who are scofflaws will be detected and have some punishment. So all of these are the three key, I think, factors affecting compliance.

Again, though, it comes down to, well, what do you, as regulators, have in your toolkit to shape those things? There's different enforcement styles. This comes through in a wide range of studies throughout the literature on regulation and regulatory enforcement.

One style is known as problem-solving, engaging with people who might be not complying or maybe have challenges with complying, and helping work with them and giving them advice, persuading them to follow the law. At the other end is an adversarial approach, a second approach, adversarial, which is throwing the book at them.

And then a third, which has been known as responsive regulation, is often dynamic. It's often described as a tit-for-tat strategy. Start with number one, a more collaborative approach, but then be prepared to engage and use the levers that you have that are deterrent when that initial collaborative approach is not reciprocated.

And one way of thinking about this is through a very famous pyramid of sanctions where one can start at the bottom through persuasion, through letters, civil penalties, all the way up to license revocation. Now, not every regulator has all of those tools in their toolkit, but the point is to think about, if you want to

take that third approach, that responsive regulation, can we start off with a more persuasive problem-solving orientation and then ratchet up as needed?

Again, these are the tools that you have in any model of regulatory performance. Now, this is a very simple model, of course, right? I haven't even told you exactly how to think about your substantive outcomes, and there are many of them, any regulator has many of them.

So as you journey toward regulatory excellence, the first step is really to build out your model, to have conversations within your organizations about, well, how do we define our substantive outcomes that we're aiming for?

What are the intermediate outcomes that are leading to those ultimate outcomes of concern? Build out your model, and that model might be, and it probably almost always will, look a lot more complicated than what I showed you. Then scope out and ask, throughout my organization, given the model that we have, how well aligned is each aspect of that with the values of utmost integrity, stellar competence, empathic engagement?

And then, once you've done some scoping, then you can select strategic priorities. You won't be able to work on everything all at once, but identifying key areas to improve is part of a strategic planning process.

And then constantly assessing and measuring and seeking to continuously improve, that this is an ongoing process. Let me just say something here briefly about the scoping process and give you a framework, again, a general framework in which you can think about excellence scoping. And the way I've laid this out is I've taken that model of regulatory performance: your organizations, your actions, and your performance.

So the two parts that are directly under your control and then the ultimate part, performance, put that all arrayed horizontally and then vertically, think about all of those attributes of regulatory excellence.

And I've just put down the three main core atoms of excellence and the three tenets for each underneath. And one could then, just through even a traffic-signal-like fashion, go about scoping your organization and seeing, well, how well are we doing in different dimensions of this, of our model against core values of regulatory excellence?

And this can then help guide strategic priority setting. Okay. Now, remember those actions that you have available to yourself, the parts of the organization you have control over.

These are the keys to regulatory excellence. This is what was in that red square on the left of the model. The people in your organization, internal management, priority setting, problem-solving. Problem-solving is often the everyday work that a regulator does. And then the public, the external engagement.

And that leads to performance. And I guess because I'm at the Penn Program on Regulation, I'm partial to something that has a lot of Ps here. But I really think that these are really core to achieving regulatory excellence, to what you do. Not just the attributes of regulatory excellence, but these are the actions that you have some control over.

Now, in our final report, and I won't go through all of them, we list some key questions to ask yourselves, as leaders within your organizations, how well you're doing in these keys to regulatory excellence. So for priority setting, here are six questions.

Are you seeking out state-of-the-art evidence in making both regulatory and management decisions, and then incorporating that evidence in good faith into your decision-making? Do you actively investigate and seek to generate new knowledge of poorly understood risks or potential areas of concerns or regulatory impacts?

So forth. I won't go through all of these, but these are there in our report if you want some food for thought, some questions. We have the same for problem-solving. We do this for the other Ps as well. Now, I want to just spend a little bit of time talking about problem-solving first, and then get to some thoughts about risk and priority setting.

There's lots of threats to sound problem-solving that any organization faces, certainly regulatory organizations among them. One is what sociologists call garbage can decisions. This is when solutions go searching for problems rather than the other way around.

And let me assure you, by the way, that I don't mean to insult any organization by calling these garbage can decisions. First of all, that's the term that the sociologists give it. And second of all, the sociologists came up with their theory of garbage can decision-making by studying decision-making within university settings.

But it can afflict any organization. Solutions can go searching for problems rather than the other way around. There are certainly concerns about myopia. This is a human tendency of shortsightedness. We are focused on the issues right in front of us rather than those that are farther down.

NIMTOF, I don't know how many of you have heard of NIMTOF. Maybe some of you have heard of NIMBY, not in my backyard, right? But NIMTOF is not in my term of office, and it's a type of myopia, a type of short-term thinking.

As long as I can get through the hard decisions, I can pass along to somebody else. There's lots of concern about organizational overlaps, and as I noted at the outset, licensing boards are just one part of a larger complex web within the whole healthcare delivery system and quality assurance of that system.

So organizational overlaps can really make things challenging. Regulatory capture is always a concern in regulation, that regulators will come to identify much more with those who they are regulating than with those who they're supposed to be protecting or who will benefit from their regulation.

And then there's a host of biases of cultural, or racial, or gender that can be afflicted. The excellent regulator tries to rise above these and tries to think down the road, beyond the horizon. And that is something that I want to just illustrate with an example from a related aspect of medicine, if you will.

This was a case study that we've done of child-resistant packaging of medicines, which everybody's familiar with today. But when the federal government first issued its standards for child-resistant packaging of medicines, because there was an identified concern about childhood poisonings from medications that were issued to people, put on their counters or in their bathrooms, that children were getting into and easily opening and harming themselves by exploring and digesting them.

So what were the first regulations designed to do? They were designed to make sure that children couldn't get into them. And there was actually a test, a test that said manufacturers of these packages, "Give these to a sample focus group of children, show them how to open them. And as long as no more than a small percentage of children could open them after you show them how to do it, it'd be child-resistant."

Great, we solved that problem, right? On the contrary, those packages that turned out to meet those initial standards were also hard for many, many adults to open. Many adults who were older, who probably had more medications and were frustrated.

And once they finally did get those packages open, what did they do? They either left them open or they put them in some other container, and childhood poisonings actually increased from... And it took 13 years for the federal government to modify the standards.

This is going back now to the 1970s, okay? So it's maybe not in our immediate sphere, but 13 years before they put in a standard that said, "Okay, you've got to both run these packages through focus groups of children and make sure they can't open them, and then run them through focus groups of adults and make sure they can open them."

Myopia. We often have a tendency to focus on just the problem at hand, children being poisoned, and not the other dimension, also adults being able to open it. So in whatever sphere you like, I mean, just ask yourself, what's your equivalent of this child-resistant packaging example?

Are you focusing on one dimension to the exclusion of others? Broadly look ahead and look far and wide. Okay. Let me just say a few things about problem-solving now by way of how to conceptualize it. It's not how it actually always works in practice.

This is an idealized version. It's somewhat adapted from a very widely used framework developed by Gene Bardach at the University of California, Berkeley, recently passed away. And it starts by just what probably makes sense, is it's the opposite of garbage-can decision-making.

It's focused not on the solutions looking for problems, but focus on the problem: defining it, understanding the problem. Is it getting worse? Is it getting better on its own? Who's causing it?

Where is it coming about? And only when you really can define and understand the problem can you hope to solve it effectively. Then you can... The second step is identify alternative solutions, not all of which you will adopt. And one of those solutions might be... By the way, one of those alternatives, at least, might be, well, not to do anything.

Maybe the problem's not so big. Maybe the problem's getting better on its own. Maybe any of the other alternatives might be worse. And how do you know if the other alternatives might be worse, or how do you know which alternative might be best? Well, it's to select some kind of criteria for choosing among them.

Once you can identify, well, is the criteria just to keep kids from opening packaging, or is it the criteria to keep kids from opening the packaging and adults able to open the package? Right? Those criteria are really important.

And then analyze your alternatives that you've identified against those criteria, make a decision, implement that decision, and then evaluate performance, full circle. This is an ongoing thing. Even though it's listed as linear, it's not linear. Even though it seems static, it's not static, it's ongoing.

Let me just focus on, for a moment, alternative solutions and highlight that even for regulators, not all of the solutions are regulatory. Sometimes, thinking outside of the box, think about warnings or alerts, public education, education of regulatees, hotlines, letters, phone calls, voluntary efforts, and so forth are not strictly regulatory by way of rules and their enforcement.

And there may well be what you want to consider by way of alternative solutions. But even regulatory solutions, rules, and their enforcement have alternatives. Alternative rule designs and structures, alternative stringencies to rules, and alternative enforcement strategies.

How do we target some problem areas? How do we prioritize? What kind of investigative techniques do we use? Do we use a throw them the book at them kind of approach to noncompliance? Or do we use the more problem-solving approach? So lots of alternative solutions to consider, both regulatory and non-regulatory.

That's about all I'll say for those right now. I want to move to the analytic criteria part and think about criteria for problem-solving. And these criteria can be used for choices about various programs you have in place or want to put in place, various policies, procedures, practices.

Basically, what are the criteria for any choices you have that are related to your efforts to protect those patient populations you're seeking to protect and protect the public? Criteria can be used both prospectively before you make decisions.

They can also be used after the fact to evaluate how well things are going, okay? Now, one thing to note is it's always going to be relevant to have a criterion of what would be called impact or effectiveness.

That is, what's the core problem these solutions are aiming at? And how well does it do with addressing that problem? That's pretty straightforward. The real challenge I think often is, well, what other criteria to include? Other common criteria, other than effectiveness, include cost-effectiveness.

And what is that? That just means, in the economist's language, thinking about your lowest-cost option for attaining a goal. This is very akin to the right touch view of doing only what's necessary, right? So thinking about the lowest-cost option, or sometimes it's a way of thinking about, among your alternatives, which is the lowest cost per unit of problem solved.

Sometimes we have cost per life saved, cost per quality life saved. Those are cost-effectiveness measures. Costs in this criteria are considered, but they're not being balanced necessarily against benefits, okay?

When you balance, then we're looking at a criterion that would be called efficiency or net benefits. This is taking the benefits from a particular option, subtracting the costs, and the most efficient option would be the one that delivers the most net benefits. And by the way, let me just urge you to avoid thinking about benefit-cost ratios if you go down this road.

Why? Just think about it. A ratio of 3 to 1, okay? That sounds good, right? We've got three benefits to one, three units of benefits.

Maybe we monetize them: $3 worth of benefits to $1 worth of solution. That's not better in terms of net benefits than a 200 to 100 solution, right? So if we've got alternatives and we're trying to compare them, ratios, you got to be really tricky about because the first one has a higher ratio than the second one, but the second one actually delivers much more value.

All right? So one might say that in the end, maybe a benefit-cost analysis, somewhere balancing the benefits and the costs, is inevitable. This is actually the view of one of the earliest leading economic texts on benefit-cost analysis, who the author says treats benefit-cost analysis as nothing more than just a weighing of the pros and cons of a decision, or as those of us at the University of Pennsylvania, which was founded by Benjamin Franklin, like to say, is just a matter of prudential algebra that looks at the pros and the cons before making a decision.

Now, taking benefit-cost analysis seriously does lead to a recognition that there are optimal levels of problems. And maybe for some of us, that might seem problematic. The idea in the economic sense here, and this is illustrated in this table, is that one looks at the level of the problem, the marginal benefit from solving a problem as you go from 0 to 100.

Maybe think of this as more stringent regulation, putting more investigators out there or what have you, or clamping down more firmly on the nursing profession with stringent regulations. Maybe that's going to really capture more and more of the problem. But the early gains are usually with some initial efforts, and the marginal benefit, the additional increment of benefit from going farther and farther down that horizontal path here on this chart, tend to decline, and the costs, though, increase, right?

How many investigators can you hire? Right? Those are going to increase, and there's going to be a point at which these two lines intersect. And from a standpoint of economic efficiency, this is a point of optimality. And it's going to leave some degree of problems still there, okay?

And lest you think that this is just a function of economists in their own theoretical spaces drawing figures like this, I would just point out that the Professional Standards Authority in the UK, in their latest report on right-touch regulation, I mean, this is what right-touch regulation, in some sense, is all about.

It balances, it says, "The scale of regulatory interventions against the risk of harm." Too little is ineffective, too much is a waste and may impose unnecessary burdens or costs. So this is another aspect of climbing up that knife's edge, that arete of trying to balance and find the right level of public protection in a world that insists often, especially after the fact, that there be total public protection.

Now, I've given you a couple of criteria, cost-effectiveness and efficiency, that can be thought of either in addition to or as alternatives to just looking at impact or effectiveness. Other criteria may matter too. We can list these.

And really, again, this is part of the hard task, is choosing the values. Maybe acceptable risk is a criteria. Feasibility, which is a way of thinking about what costs are acceptable. Taking into account the administrative or paperwork costs. The enforceability or administratability to you, the regulator, matters in choices prospectively.

Maybe you want to think about how what you're doing is going to affect innovation in the healthcare setting. How will it affect competition? Do you have legal authority? That's certainly going to be a criterion that matters. What about political considerations?

Maybe that's not so comfortable to think about. And there may be more. The key is that problem-solving begins with not only understanding the problem, not only understanding alternative solutions, but then doing the hard work of saying, "Well, how should we decide, and how should we choose among those alternatives?

What are our values? And that's what the criteria are all about. Let me shift gears now yet again to think about priority setting and to risk. And it is widely said in the world of regulation of many, many spheres that regulators should be risk-based.

Here's a leading scholar who's a British scholar who's focused on regulation in a wide range of areas, who recently published an interview with our publication at the Penn Program on Regulation, The Regulatory Review, in which she extols the virtues of risk-based regulation.

What is risk-based regulation? For her, it's targeting regulation and regulatory efforts on things which pose the greatest risks to society or to regulatory objectives. Sounds great. I don't disagree with that. I probably would have a hard time finding anybody who would disagree with something like that. It's about calibrating regulatory requirements so that more onerous requirements are placed on those activities which are thought to pose the greatest risk to society.

Sounds sensible. Common sense, right? And this again is reflected in the right-touch philosophy and framework that the Professional Standards Authority articulated. That first principle was proportionality, and it depends, the PSA says, on the proper evaluation of risk and making sure that regulation is proportionate and outcome-focused.

Most recently, it says one of the key strengths of risk-based regulation is that when it's used well, it provides a clear, transparent, and rational basis for determining what and how to regulate. These are all good things to keep in mind, I think.

But let's try to unpack these a little bit, so to speak. Let's start with what is risk, really. And this may well be familiar already, so I'll go through this relatively quickly. But risk is formally a mathematical equation of probability times the value of a consequence.

Probability of some adverse happening times the value of that. Probability of an acquired hospital infection times the health consequence of that infection. In the regulatory context, the consequences are negative.

They're hazards, right? They're the things we want to try to prevent, all right? Let me just say that this concept of risk contrasts with uncertainty. What is uncertainty? Well, risk is measurable and probabilistic. We can actually do that math problem.

Uncertainty is unmeasurable or unknown. And this is a common framework for thinking about the difference between risk and uncertainty that goes back to the early part of the last century, by an economist named Frank Knight. And there are different types of uncertainty, most famously characterized by a former defense secretary, Donald Rumsfeld, who talked about the known knowns, those things that...that's risk, and then the known unknowns, that's uncertainty that we know there's an issue, but we just can't really put it into those mathematical terms.

And then there's also the deep uncertainty of the unknown or unknowns. Sometimes this has been characterized by experts in the field as the difference between known unknowns and unknown

unknowns is between subway uncertainty. You know that the train's going to come sooner or later, but you might not know exactly when it's going to come, versus coconut uncertainty.

You're sitting on the beach under the shade of a palm tree, not even thinking about the possibility that that coconut up there might fall on you. So the key for regulators in priority setting is to assess risks. What is risk assessment?

It's characterizing the nature and size of that risk, trying to get that uncertainty down and into a mathematical equation. This is a common risk assessment framework which focuses on the left on hazard identification. You got to know that there's coconuts up there, right? Think about dose-response evaluations, health, and exposure assessment.

These are ways that probability will increase. And when you have that, then you can do the math and characterize the risk. And then on the right, manage the risk and communicate about it. But risk assessment really is what's on the left. Risk management is what you do about it.

This is a common framework called the Bowtie Framework for Risk Management that focuses on prevention. That's what a lot of regulation is about. But the Bowtie also remembers that in the middle, when that adverse event happens, thinking about recovery.

Interestingly, I mean, from the standpoint of society, nurses and healthcare professionals are often on that right side. An automobile accident happens, and one of the reasons why automobile accidents produce fewer fatalities today is not only because cars are being built safer, but because we have better EMS systems and better medical care.

After the accident happens, we can recover. But for regulators, it's often at the beginning, the prevention. And so we can ask, what is a risk-based regulator? What is a risk-based regulator? You've heard this. Maybe you're committed to it. You may have your own thoughts about what that is.

Here are just some key questions, though, I would urge everybody to consider. First of all, risk to whom or to what? There are some folks out there that view risk-based as being, let's think about the risks to my organization. And I would submit that for regulators, the key is to think about risks for the public or for those segments of the public that you're protecting.

Then ask, what are the decisions that are supposed to be risk-based? It could be the making of rules. It could be the enforcing of rules. It could be both. And then, and this is where I really want to highlight, what are the specific values that should guide risk-based regulatory choices?

Risk-based often sort of makes it seem like, well, once we just figure out the risks, then everything else follows. And first of all, that's hard because there's often a lot of uncertainty as well as risk, okay? But even if you know and can compute the risks, even if you can say these are the greatest risks because we have an ability to quantify them, maybe we have the ability to monetize them even, how do we choose among them?

Now, to help illustrate this conundrum that needs to be confronted, if you want to be a risk-based regulator, you can't overlook fundamental choices. Let me give you a very, very simple set of four choices to take. You can think about this as four different alternative rule designs or rule stringencies.

You could think about this as four different investigations to pursue. Which one do you choose if you're a risk-based regulator? I'm giving you information that probably is more concrete and definitive than you'll ever get.

But nevertheless, even with that information, how do you choose? Well, you've got here information about the probability for option A, option B, option C, D. Probability is in that second column.

That's the first part of that mathematical equation of risk. And then you've got the hazard, the value of the consequences. It's negative because, again, these are bad things that are trying to be avoided. The benefits column, the third column, is just really the probability times that hazard and then with the sign reversed.

Because if you choose that option, the assumption is going to be you're going to target it, and you will eliminate that hazard, okay? You will eliminate that risk. And you'll reap the benefits, which is the probability times the hazard times negative one.

Reverse the sign. And then I've just stipulated some costs. And then I've computed the net benefits, right? Because that could be a criterion that you choose if you want to go down the efficiency route. All right. So what do you choose? What do you choose?

Well, it depends on your values. If you want to eliminate the largest hazard, if that's what you're going after as a risk-based regulator... And, of course, risk-based doesn't tell you whether...is that what risk is? Well, you're going to choose option A, obviously. It's the biggest hazard.

It's up there at first, okay? But what about the largest risk? The greatest risk? Well, the greatest risk is probability times the hazard. Which is the biggest risk here? Well, that's option B, okay? What if you say, "Well, we want to just try to regulate maybe right-"touch fashion until the costs get too high?

And I'll just stipulate here, for sake of illustration, and that's all this is, that maybe the costs get too high when they're over 25 here. Well, then you've got options A or D, okay? So you've got different options. Now D comes into play.

How about if we avoid an unacceptable risk? That is, something that's less than negative 25. This is probability times hazard, which would be negative. You don't want anything worse than that, because that's unacceptable. Well, then now we've got options B or C.

What if we choose more of a Hippocratic oath, or do no harm? Well, maybe that's no option, because all of these come with costs, and maybe that's not compatible. One would say that would not be Pareto efficient, because all of these options have some kind of cost associated with it.

Or we could say maybe we choose B or D, those that have positive net benefits, because in the end, we're actually doing something that's beneficial positively. Or what about the efficiency test of maximize net benefits? Well, which one is that?

That's option D. You're risk-based with any of these, right? All of these are decisions that you're making based upon the risk information I've given you here. But which one you choose depends on the values that you're selecting. And just saying risk-based doesn't necessarily predetermine what that value is.

And fortunately, I think in the right-touch framework, this is now recognized, that 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. So think about that. This is actually something that I wrote about earlier in a different context and pointed out that rather than just providing a clear principled guide for regulatory decision-making, a call for risk-based regulation only necessitates other choices with real policy implications and for which there might be few uncontested, determinative principles.

So we've been focusing on problem-solving and priority-setting prospectively, making choices about where to target, where to put our resources. Now, in the remaining little bit that I'll speak about, let's look back. Let's look in the rearview mirror.

Let's think not just prospectively about what to do in the future, but retrospectively about how choices we might have made, choices that we are making, and programs that we are operating, how well they're working. And measurement can serve many different purposes.

It really can. And I won't go into all of them, but I do want to emphasize that the most important purpose is to learn. To learn. And that's to learn, by the way, not only about the successes but the failures. To learn about the good, the bad, and the ugly, to quote from an old spaghetti Western.

Because it's possible to learn from failures as much as, maybe even more, from failures than from successes, okay? One of the key things about measurement, and we know this from a variety of different contexts...

And there's a wonderful chapter by Don Moynihan, a public administration expert, in my book on achieving regulatory excellence, on performance measurement. And he cautions highly against putting high-powered incentives on goals that you can only measure imperfectly when you're measuring. Why gaming can occur.

You can end up with outcomes that are perverse because people act strategically. So he says build learning forums. And I think that's really important. As you go to measure, also think about what are your metrics? And again, this is discussed more widely in my chapter on measurement in achieving regulatory excellence and in our final report that I mentioned earlier.

But metrics need to be relevant. Obviously, this makes a lot of sense. There is the old aphorism about the drunk looking for their keys under the lamppost. Why are they looking there? Because that's where the light is. Well, not necessarily relevant.

You've got to think about whether the measures are relevant, related, and tightly connected with what you're trying to measure. Are they reliable? They have to be accurate. They have to be resistant to manipulation. And of course, they have to also be realistic.

You do need to have some availability. They need to be intelligible. And by the way, measurement is not something to think about separately from regulatory excellence. Measure with the utmost integrity, with stellar competence, and with empathic engagement. There's nothing to say that you can't engage with others as you're choosing metrics.

Now, metrics is only part of the issue, though, when you're looking backwards. You also have to think about methods, methods of assessing how well you're doing. And there's three kinds. One is just to do what is often called bean counting, but that is just to focus on the actions that you're undertaking.

Bean counting makes it sound almost pejorative, but I think it's important to know what you're doing. But you also have to focus on outcomes. Is the world of healthcare quality improving? What are the specific challenges that you are confronting? Are they getting better, getting worse?

But even that's not always enough, though. The connection between your actions and your outcomes, that's critical. That's what we call causation. Are your actions causing an improvement in outcomes? And that's really critical. Remember, again, linking these measurements to organizational incentives is something to view with great deal of caution.

But here's an action measurement taken from the federal environmental regulator, looking at the number of inspections that were conducted. That's an action measurement. Even this, the number of civil penalties that were issued by the U.S. EPA in a given year. Again, action measurement.

These are the things in that red box at the beginning that you have control over, you're doing. Important to measure, right? But what about the outcomes? And here's a measure of air quality indicators for major categories of pollutants over time. What do you see? They're going down. That's a good thing, but is it because of those actions, or is it because major manufacturing has shifted overseas?

We have an economy that's much more based upon service delivery, healthcare delivery being an important aspect of that. That's why causal attribution between actions and outcomes is so key. And only with that kind of what I call attributional evaluation can anybody answer the fundamental question of how well regulation is working.

There are some basic strategies for causal attribution. I won't go into all of them here, but the basic idea is to measure the world against a counterfactual, against a world in which you didn't undertake the action. In the laboratory setting or in medical research, we can actually separate patients that receive a treatment from patients that don't receive a treatment.

In the regulatory world, that's often hard to do. So we have to estimate a counterfactual, and there are techniques for doing that. Those techniques exploit variation, variation over time and variation across jurisdictions. So one could compare before and after, one could compare in one jurisdiction versus another.

Lots of techniques for doing that in a very sophisticated way today, and important to keep in mind. Now you can't do this kind of causal evaluation for everything you're doing, but I would urge you to think about, in addition to measuring actions and keeping in touch with outcomes, you do two things.

One is think about things in a causal attribution way. Try to ask how much of our actions are what's really causing this, and then, for at least some things, when the data are available, when you can work, maybe partner with some researchers in a local university or whatever, maybe you can do some causal attribution evaluations.

And then another thing I would urge is to think about bringing that insight from measurement back into decisions that you're making. So post-evaluation, feeding back into ex ante decision-making, and keep measurement ongoing. Computer software is shifting from waterfall development of design and implementation, and this actually maps on to a way that a lot of regulators have approached their work.

Rules get set, and then we implement and enforce them, to thinking more in an agile way in which, yes, rules are put in place, they are implemented, and then we're learning how they're doing and cycling through on an ongoing basis, trying to seek continuous improvement.

Agile is part of right-touch regulation. It's also important to recognize that agile is important because the world keeps changing. Medical technology is changing.

People are changing, and their values are changing. And I wrote a paper, published a paper recently, in which I urged that we think about regulation not as something static but as a verb, and obviously this is something that, in your materials on Regulation 2030, you recognize that regulators can't be dormant in light of the rapid change in what's happening.

What's happening is that data are growing vastly in all spheres of life, and certainly in medical records and medical technologies they are. And in the world of regulation, artificial intelligence is increasingly being used by regulatory officials, and you're probably facing that yourself.

Some uses for artificial intelligence in the world of regulation is to prioritize, to make forecasts about who's best to investigate, who to prioritize, who to educate. There's even some research that suggests maybe artificial intelligence can be used to identify those practitioners who are posing greater risks to patients.

This is where we're going in the world. I'm happy to explore this in the time that we'll have for questions here in a moment. Let me conclude by saying that, of all the things that I've been talking about technology and data, data being data driven, really important.

I wrote a paper called "Regulating by Robot," even, and I recognize that as technology is moving fast, regulators need to be exploring that technology and trying to keep up with it. And yet, let me bring it full circle here and conclude by noting that most important of all, regulatory excellence is people excellence.

It's all of you being here. I thank you for your attention this morning, and I thank you for your leadership within your organizations because it's the people in those organizations and your teams, if they're committed to the utmost integrity, to stellar competence, to empathic engagement, to being data-driven, sure, to being risk-based, yes, to being right touch, absolutely too.

All of these are important dimensions of the task that you have to protect the public. I thank you for all that you do throughout the year, and I thank you for your attention this morning. And I leave the rest of our time for some questions.

Thank you very much. And I'm told you can walk up to the microphone, and someone will put a spotlight on you, and I'll be happy to entertain any questions that you might have.

Or I'm realizing maybe I'm standing between you and a coffee break, or... All right. Oh, where's mic 11? I'm not sure. Okay, mic 11.

- [Vicky] It's looking the wrong way.

- Go ahead.

- Hi, my name is Vicky Byrd. I'm a registered nurse, and I'm the CEO of the Montana Nurses Association. And so thanks for your presentation on regulation. However, concerning AI, how do you

ensure that AI doesn't completely remove the human factor in some of these decisions that impact us as humans?

- Well, I guess there's a couple of things. One might be... A couple of thoughts that I have about this. One might be to push back a little bit on the question and say maybe there are some things where there's human factors that should be removed, okay?

And by that, I just mean to say that when thinking about artificial intelligence, I think the key question is: compared to what? And humans have... Artificial intelligence has its frailties. It can be biased.

It can hallucinate. It can be error-prone. But those are all qualities that define humans, too. And the real question then is, are we going to do better with artificial intelligence? One of the challenges also in answering that question is that what counts as artificial intelligence is a highly varied thing, right?

It's certainly these large language models that we're all familiar with now: ChatGPT, Claude, Llama, Gemini. But there can also be...there's a recent report just on the news yesterday, a very targeted artificial intelligence system that a cardiac specialist was doing to identify risk profiles for patients that might be useful in helping inform human-delivered medical care.

So some things might be good to replace or supplement. It's always compared to what? And I guess I would say that that's probably the best way I would urge us to think about keeping humans from over-relying on artificial intelligence is to really think skeptically and critically about what do they do that might be better and what might they have problems with doing.

And if they can do some things better, by the way, I think we ought to definitely embrace that. And it might even, that embrace might even free up humans for doing what they can do best, which I think is empathy and care, gentleness and concern in Atul Gawande's terms.

So the future is one in which I think we're going to have to navigate. The question you ask is exactly the one that should be on everybody's minds all the time. And maybe asking that question is the best way of ensuring that we go forward without over-reliance on artificial intelligence, but also without over-resistance to it.

- [Philip] Is it me?

- Mic number one.

- I think it was her. I think number two should go next.

- All right. Number two.

- [Claire] Hi, Claire Morris, executive director from Virginia. One of the things that we've noticed at our board is we have definitely an uptick in cases over the last couple of years. And it's as if our licensees just have decided, I'm going to do what I want to do when I want to do it. And they're not showing remorse.

And I've talked to my colleagues at other boards here in this room, and some of them are saying the same. So I'm curious, and maybe you don't have any information about this, but is your organization seeing that across all parts of industry?

- Well, I do think it's related, or at least my initial hunch is it may be related to that decline in public trust in institutions, public trust in medical professions, public trust in experts.

And I do think that regulators across the board are facing those kind of challenges. And one of the things that we, as a research community, are doing is trying to really put a spotlight on, and there's a lot of work going on about how regulators can build and maintain trust. And that's...

I think one thing that's different about, as I said, regulation today than maybe 30 years ago is this expanding social media environment, and an expanding environment in which there's diminished trust in institutions generally. And it's maybe not something that any one individual board by itself can solve. It's a larger societal trend.

It's something we have to recognize. And I'm glad you're thinking about that. It is something to be very much concerned about. Thank you.

- Thank you.

- Hi, Philip Dickison, CEO of NCSBN. So I have a couple of comments here that I think are particularly important, at least. And I will say that you have to have a diversity of ideas. I told you that yesterday. You have to be able to have that sort of discussion. So I'm going to give you a diverse opinion here.

First off, I'm a fan of AI. You all know that, right? I also think that AI is not artificial, nor is it intelligent. Either of those things are absolutely untrue to me, all right? We've had artificial intelligence that's grown from what is known as machine learning. Do you know you've had machine learning at the council for over 25 years?

It's called a CAT exam, all right? So I think you've got to be careful. I want to take you back to something I said yesterday. Look, I told you as you went through and thought about your job as regulators, there was a place where you needed to have the composite of evidence and context, all right? And I would argue, I also said that where trust is built is when you have accountability and compassion.

My problem with most of AI, if you just use it as simply it is god and you do what it says, is you will not get compassion. And it will always need AI and human together, AI alone. So I'm going to flip your argument.

What is it that AI can't do for you? Right? You say, "Well, we should be using AI where it can do things," right? But what can't it do? And I don't think that argument's always there. We're always sort of going, "Let's use AI, let's use AI." And I'm a fan of that.

But at what point does AI not do those things it can do? I heard the other day, they're starting to use AI because they think a massage therapist will tell them where to touch and push or put the right amount of pressure. I want everybody to think that through for a minute. Any of you ever gotten a massage? You kind of need to feel it, don't you?

Because that's where the knot's at. How's the AI doing that? Right? So I think there's got to be an honest discussion about where humans do better than AI. Now, I will argue I think controlled AI is the way to go. I argue large language models don't have diversity. If you pick Claude, there's no diversity there.

It is the large language model that has followed the patterns that it's been told to follow. And it will continue to follow those. So you have to make sure that you don't... Here's my point: you don't work for AI, AI works for you, all right? Thank you.

- Thank you very much. And I think that's a wrap for us here today. I think that last point is a way of just reinforcing how much regulatory excellence, even in a world of AI, ultimately comes down to people excellence.

So I thank you very much for your time here today. Thank you for being such a gracious audience, and thank you for all that you do throughout the year. Have a good rest of the day.