Qualitative and Quantitative Assessment of Uncertainty in Regulatory Decision Making

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Legal analysis of regulation is largely verbal/qualitative.

Economic analysis is largely mathematical/quantitative.

The Elliott and Tyler-Elliott papers exemplify the legal tradition.

I can formalize most of the verbal discussion in the Elliott paper. For example,

"Timing Regulation to Anticipated Literature Development" → Optimal Stopping
"Precautionary Principle" → Maximin Decision Criterion
"Adaptive Management"/"Recoverability Strategy" → Optimal Control
"Resilience Strategy"/"Redundancy" → Adaptive Diversification
Verbal discussion can be useful to introduce concepts, but it usually does not yield criteria for decision making.

Renn and Elliott (2011), quoted by Elliott, write

"a regulator may be well advised to wait until later to act if, but only if, (a) it seems unlikely that much preventable harm will occur in the meantime, but (b) it also seems likely that enough useful information will be developed in the meantime so that making a better decision in the future will be substantially less difficult than it is today.

Because these quantities are incommensurable (i.e., they exist in different realms and implicate different values), and because they involve predictions about the future, they cannot be reduced to a precise formula.

But it may be helpful to frame the issues in this way nonetheless, because there are many “easy cases” in which it is clear that the harm that may occur in the meantime is far greater than any likely benefit that may result from waiting for more information, and vice versa."
To address the "difficult cases," economic analysis quantifies uncertainty as predictive probability distributions or bounds.

It then applies formal decision criteria such as maximization of expected welfare, maximin, or minimax-regret.
Illustration: Mandatory Vaccination

Mandatory vaccination has been a subject of considerable controversy, centered on the tension between personal freedom and public health.

Many articles in the medical and public health literatures make clear that society has conflicting objectives when contemplating whether to mandate vaccination.

These articles do not address how society might reconcile the conflicting objectives to choose a policy.
The welfare-economic practice of specifying a social welfare (or social cost) function and considering a planner who wants to optimize this function provides a formal normative framework for policy choice.

The objective presumably is to minimize the social cost of illness and vaccination.

Mandatory vaccination improves public health relative to decentralized decision making.

However, a mandate increases the cost of production and administration of the vaccine, enlarges the side effects of vaccination, and reduces personal freedom.
The specified social cost function expresses quantitatively how society evaluates these advantages and disadvantages of a mandate.

This yields a well-defined optimization problem.

Economists and epidemiologists have studied choice of vaccination policy as a deterministic planning problem, supposing that the planner knows the outcomes that alternative policies would yield.

However, a prevalent problem is scarcity of empirical evidence informative about how vaccination policy affects illness.

Manski (2015) studies the choice between mandatory and decentralized vaccination as a problem of regulatory policy choice under uncertainty/ambiguity.
Illustration: "Risk-Benefit Assessment" in FDA Drug Approval

A 2012 amendment to the federal Food, Drug, and Cosmetic Act called on the FDA to institute a "structured risk-benefit assessment framework," stating:

"Section 505(d) (21 U.S.C. 355(d)) is amended by adding at the end the following: 'The Secretary shall implement a structured risk-benefit assessment framework in the new drug approval process to facilitate the balanced consideration of benefits and risks, a consistent and systematic approach to the discussion and regulatory decision making, and the communication of the benefits and risks of new drugs."
To an economist, the term "benefit-risk assessment" suggests quantification of risks and benefits and weighing the two to measure the net value of approving a drug.

However, FDA documents summarizing approval decisions do not quantify the tradeoff between risks and benefits.

Indeed, the FDA has explicitly rejected use of formal decision analysis in drug approval.
In response to the 2012 Amendment, the FDA released to the public a document (FDA, 2013) that expresses FDA thinking. The document begins this way:

"In the past, some FDA stakeholders have indicated that there is room for improvement in the clarity and transparency of FDA’s benefit-risk assessment in human drug review. When FDA approves a new product, the agency publishes the various relevant documents . . . and decision memoranda on its website. . . .

"some have argued that drug regulatory decisions should be based on more formalized and quantitative approaches to benefit-risk assessment, including the assignment of weights to benefit and risk considerations. Others, however, are skeptical of fully quantitative approaches, and consider such attempts to be a highly subjective exercise that would add little clarity to regulatory decision making."
It goes on to side with those who are skeptical of quantitative approaches, stating:

"The term “quantitative benefit-risk assessment” can have various meanings depending on who is asked. Some hold the view that a quantitative benefit-risk assessment encompasses approaches that seek to quantify benefits and risks, as well as the weight that is placed on each of the components such that the entire benefit-risk assessment is quantitative.

This approach is typical of quantitative decision modeling. It usually requires assigning numerical weights to benefit and risk considerations in a process involving numerous judgments that are at best debatable and at worst arbitrary.

The subjective judgments and assumptions that would inevitably be embodied in such quantitative decision modeling would be much less transparent, if not obscured, to those who wish to understand a regulator’s thinking.

Furthermore, application of quantitative decision modeling seems most appropriate for decisions that are largely binary. . . .
These concerns have led FDA to the conclusion that the best presentation of benefit-risk considerations involves focusing on the individual benefits and risks, their frequency, and weighing them appropriately.

FDA believes that this can be accomplished by a qualitative descriptive approach for structuring the benefit-risk assessment that satisfies the principles outlined earlier in this section, while acknowledging that quantification of certain components of the benefit-risk assessment is an important part of the process to support decision-making.

Quantitative assessments certainly underpin the qualitative judgments of FDA’s regulatory decisions, but FDA has adopted a structured qualitative approach that is designed to support the identification and communication of the key considerations in FDA’s benefit-risk assessment and how that information led to the regulatory decision."
FDA Approval Reconsidered

The "structured qualitative" approval approach of the FDA is not transparent.

The agency makes public only a "Summary of Basis for Approval" when a new vaccine or drug is approved.

It does not make public even a summary of its rationale when it rejects an application for drug or vaccine approval.

The qualitative decision process of the FDA shields the agency from scrutiny.

Quantitative analysis of approval would make explicit how the FDA evaluates the social costs and benefits of drug approval.
Open Question

How can we constructively bridge the gap/chasm between qualitative and quantitative assessment of costs and benefits under uncertainty?

For an attempt to communicate across cultures, see Manski, C., *Public Policy in an Uncertain World*, Harvard University Press, 2013.