A Value-of-information Approach to Risk-benefit Analyses

Richard B. Belzer

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REGULATORY CHECKBOOK

Presentation Map

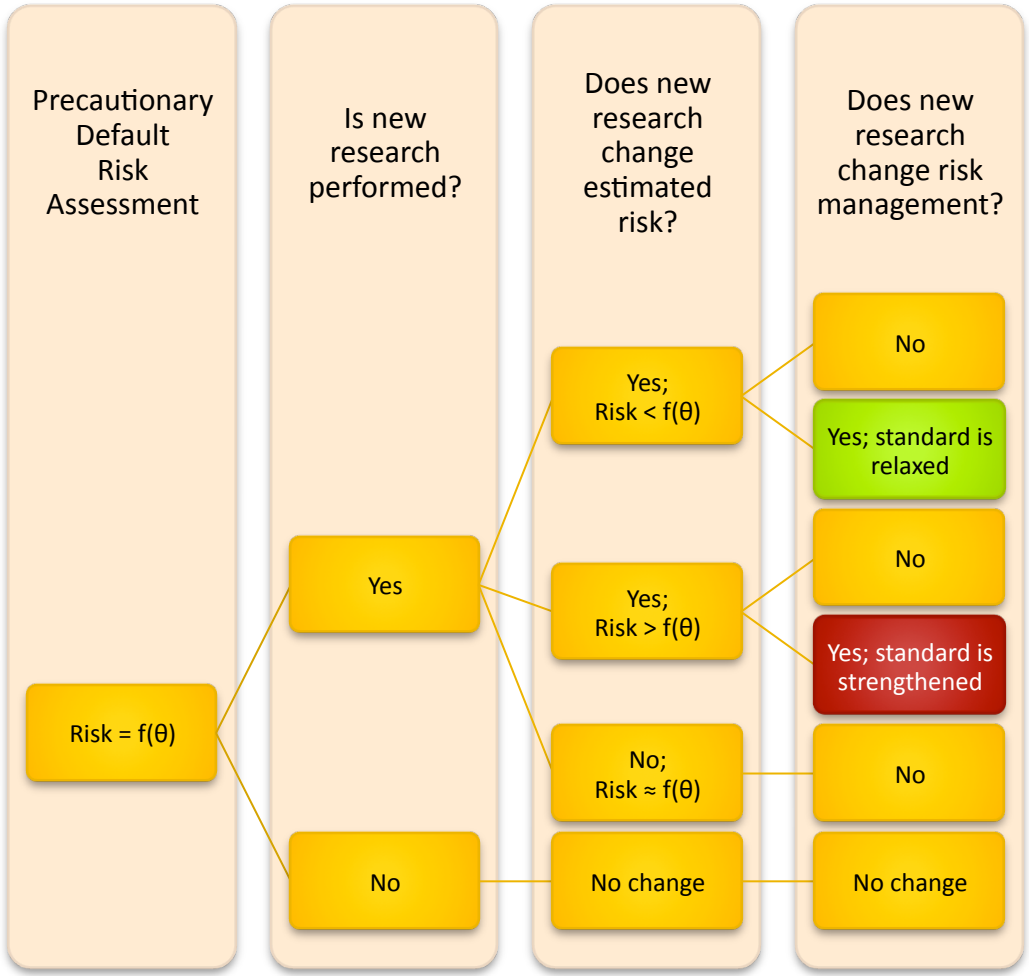
- Precautionary Principle (PP) and PDRA
- Mapping new science
  - Policy-neutral view
  - Industry view of government
  - Government view of industry
- Competing perceptions about others' research
- Research value depends on Its type and the risk assessment baseline
- A path forward
  - Policy-neutral decision framework
  - Durable prior agreements

REGULATORY CHECKBOOK

Precautionary Principle and PDRA

- PP: risk aversion due to uncertainty
- PDRA: 'precautionary default risk assessment'
- Some scientific uncertainties can be reduced or eliminated through research
- As new information reduces uncertainty, precaution in risk assessment must decline
  - If research doesn't reduce uncertainty, it cannot reducing precaution in risk assessment
  - If reducing uncertainty cannot change risk assessment, research has little or no value

Mapping New Science: A Policy-neutral View



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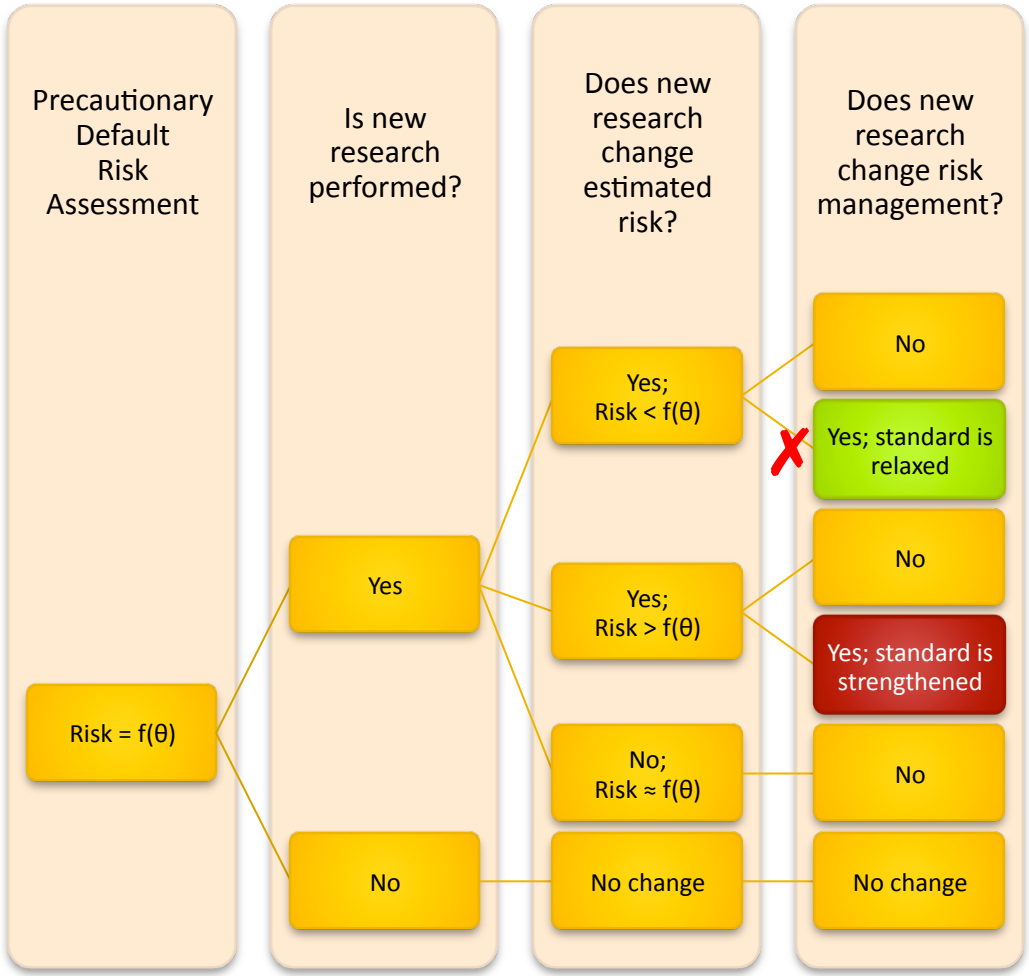
Mapping New Science: An Industry View of Government



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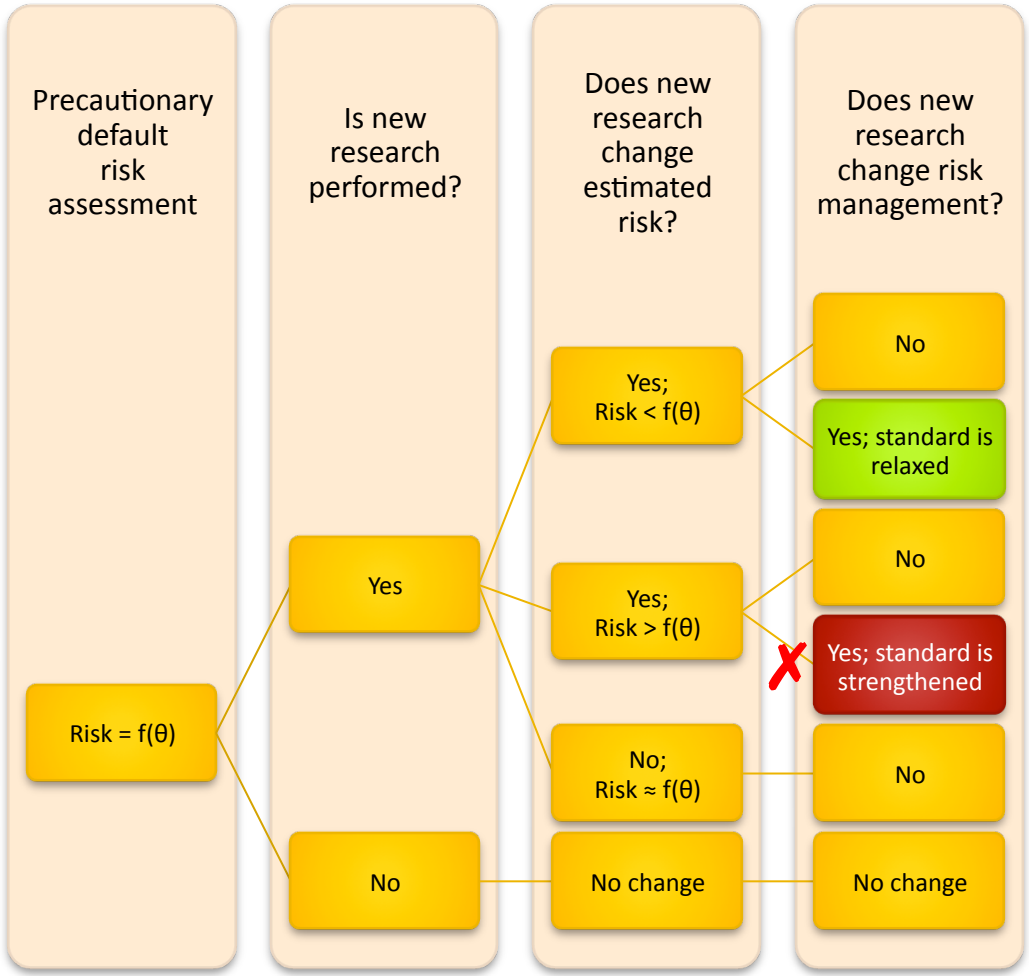
Mapping New Science: A Government View of Industry



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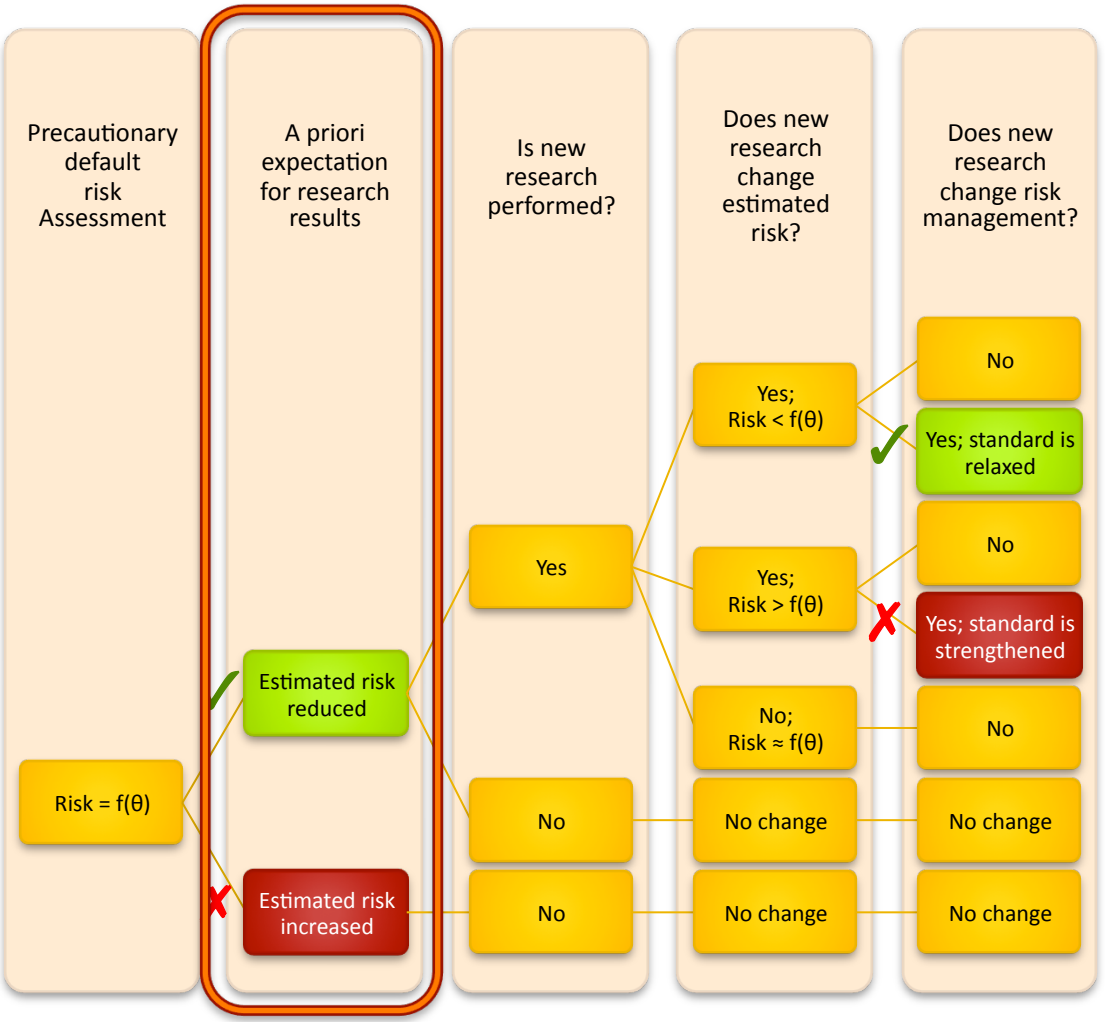
Mapping New Science: A Government View of Industry [2]



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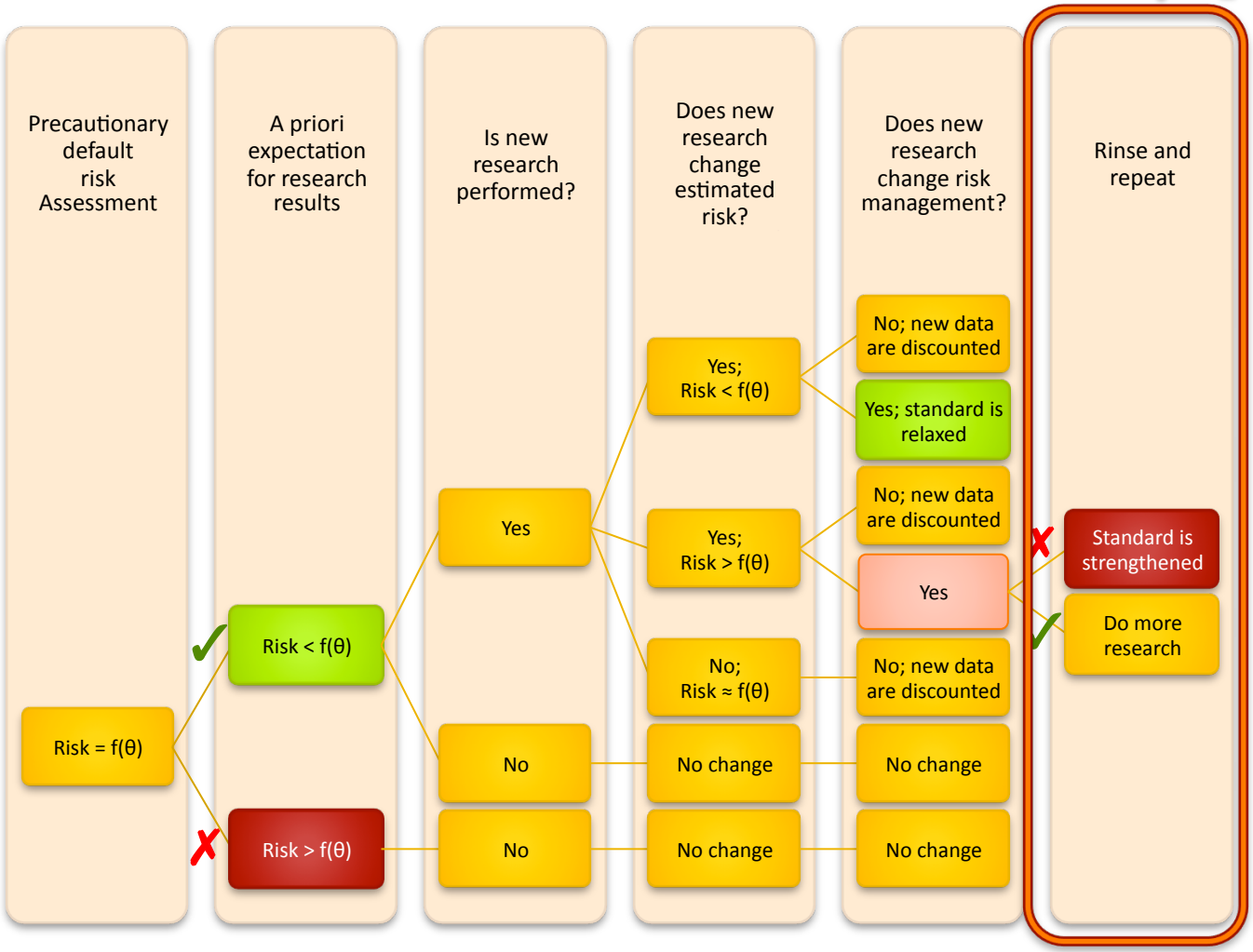
Mapping New Science: A Government View of Industry [3]



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Competing Perceptions About Others' Research

	Industry-funded Research	Government-funded Research

Industry Perception	• Policy neutral
	• Highest quality
	• Serves only the public interest
		• Biased
		• Suspect quality
		• Will fund only if it:
		  ○ Increases perceived uncertainty, risk estimates
		  ○ Justifies more stringent regulation

Government Perception	• Biased
	• Suspect quality
	• Will fund only if it:
	  ○ Reduces perceived uncertainty, risk estimates
	  ○ Justifies less stringent regulation
		• Policy neutral
		• Highest quality
		• Serves only the public interest

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Research Value Depends on Its Type and the Risk Assessment Baseline

Research Type	Precautionary Default Risk Assessment			
	Before PDRA		After PDRA	
	Can Reduce Uncertainty?	Can Increase Uncertainty?	Can Reduce Uncertainty?	Can Increase Uncertainty?
Hypothesis-generating	Yes, but unlikely	Yes	No	Yes
Hypothesis-orthogonal	?	?	?	?
Hypothesis-testing	Yes	No	Yes	No

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VOI Depends on Research Type and Whether a PDRA Is in Place

Research Type	When Most Valuable	When Least Valuable	Strongest Advocates
Hypothesis-generating	Before PDRA	After PDRA After regulatory decision	University researchers
Hypothesis-orthogonal	Unclear	Unclear	University researchers
Hypothesis-testing	After PDRA	After PDRA After regulatory decision	Risk assessors Regulatory decision-makers

A Path Forward

- Evaluate hypothesis-testing research based on pre-defined outcomes, eg:
  - H_o refuted [strongly, moderately, weakly]
  - H_o not refuted
  - Well-defined surprises
- Establish and execute durable prior agreements
  - Predictable, enforceable, and transparent
  - Strictly limited to science

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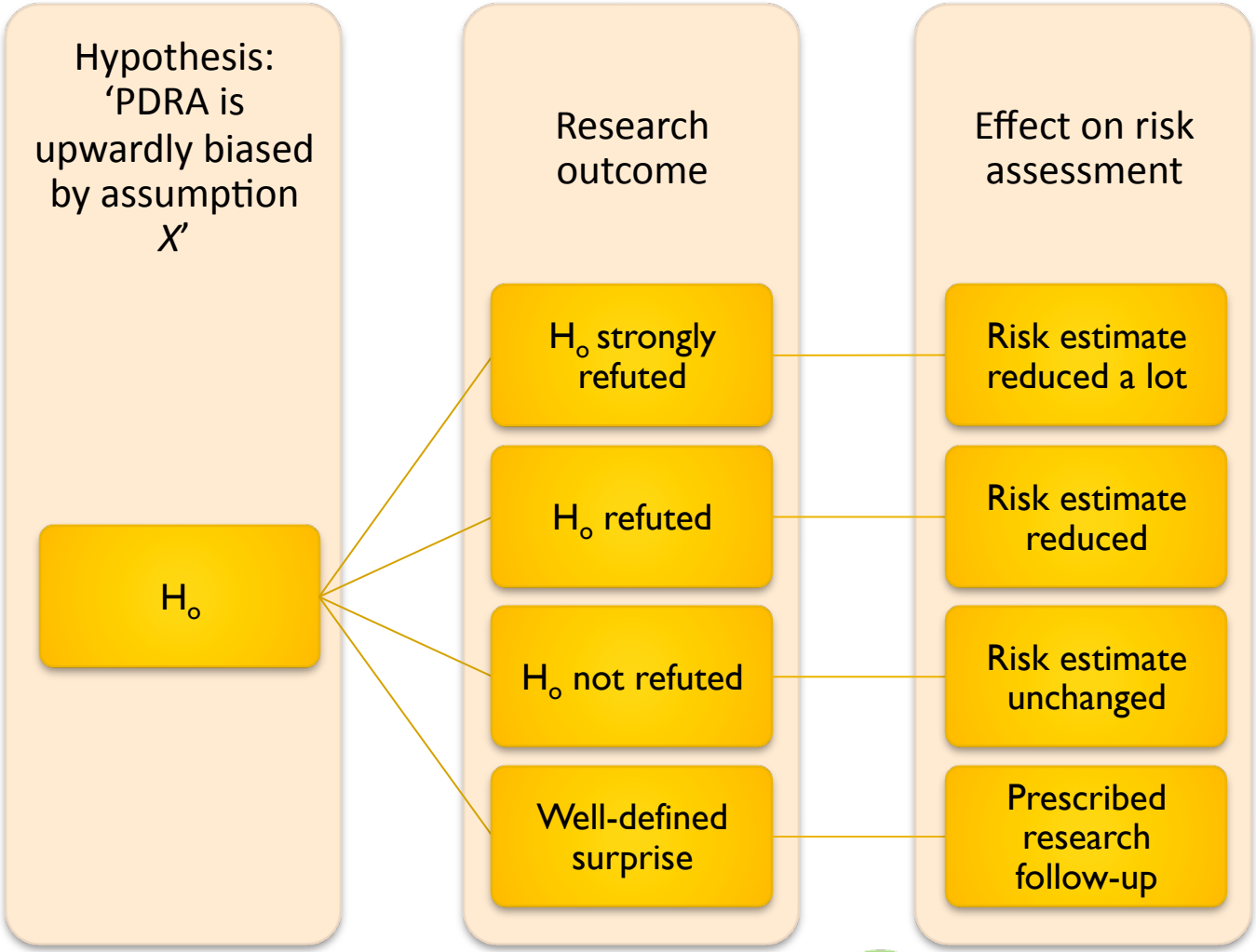
Using Results from Hypothesis-testing Research



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Durable Prior Agreements

- Establish *a priori*
  - Data collection and information quality
  - Statistical methods
  - Scientific inferences
  - Well-defined surprises
- Process requirements
  - Open access to all data and models
  - All willing stakeholders may participate (science only!)
  - Independent external validation
  - Legally enforceable

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New Science Idealized

"Bottom of the Sixth," Normal Rockwell (4/23/49)

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Richard B. Belzer
Regulatory Checkbook
PO Box 319
+1 703.780.1850
Belzer@RegulatoryCheckbook.Org

QUESTIONS?
NEED HELP?