Can Regulation be ‘Smart’ and ‘Precautionary’?

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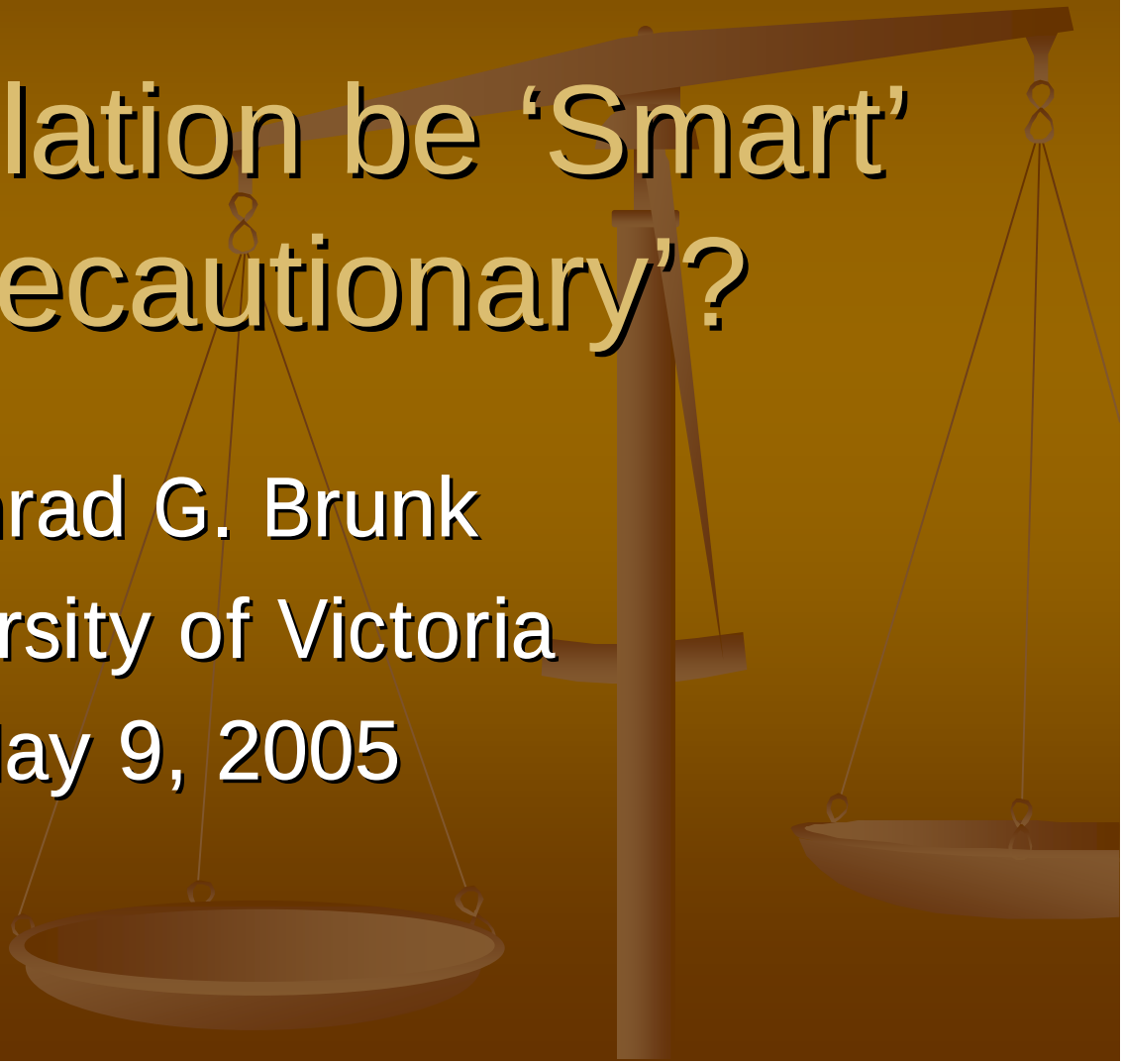
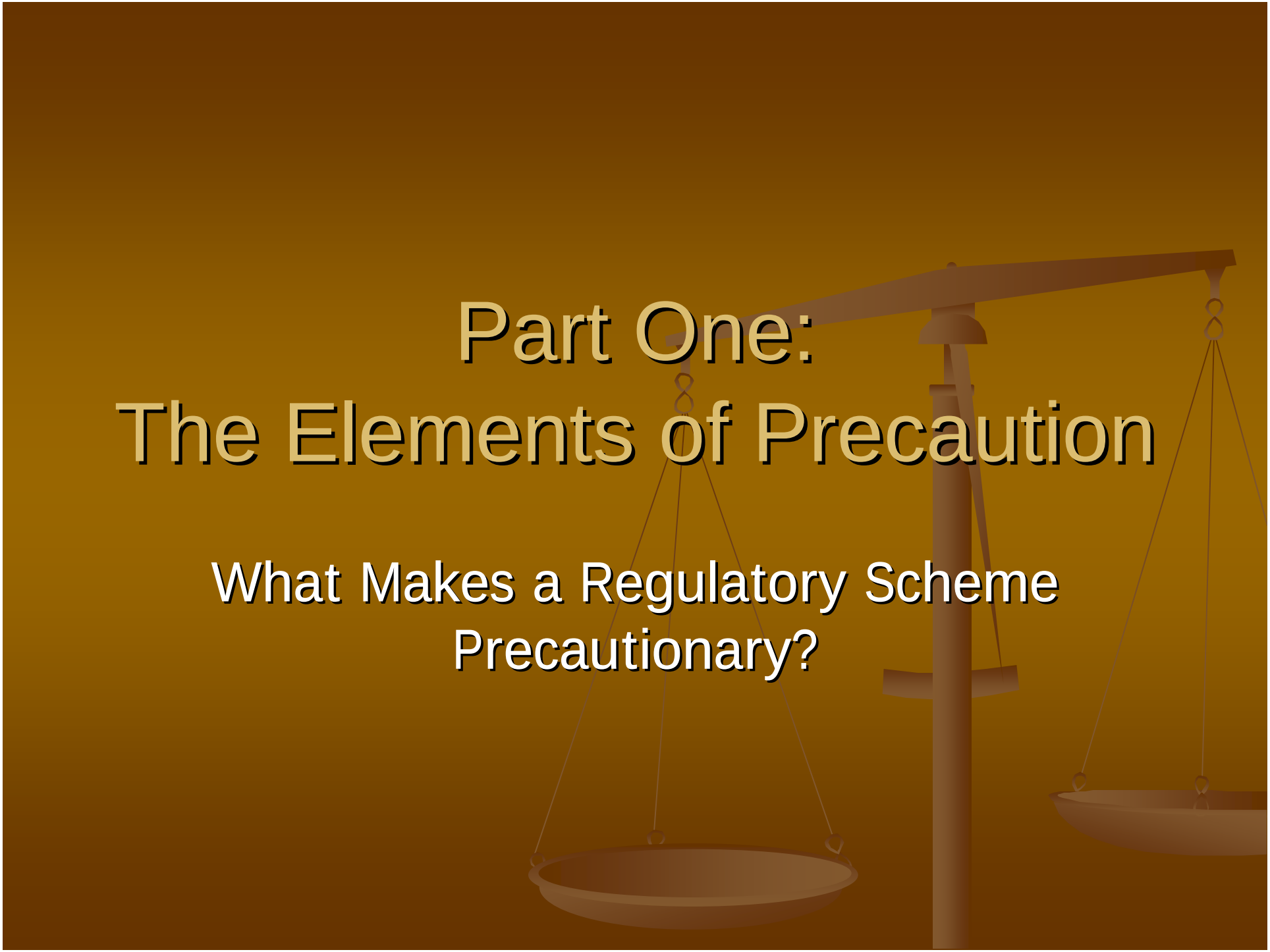




Part One:
The Elements of Precaution

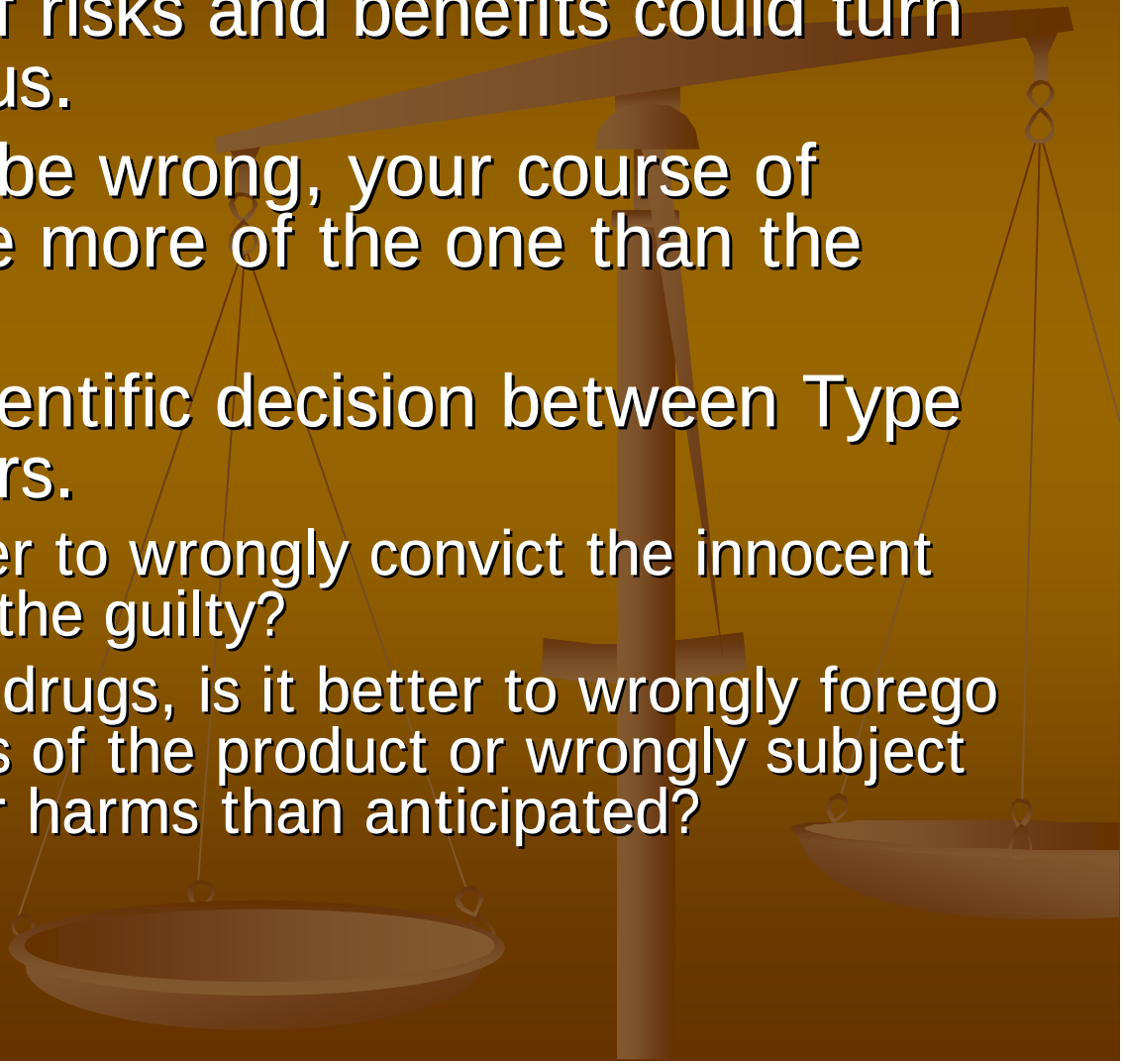
What Makes a Regulatory Scheme Precautionary?

Uncertainty of Knowledge Forces us to be Precautionary

- The ideal case of regulation – science provides reliable assessment of harms and benefits
  - We can then make a rational choice about what values we are willing to trade off for others (e.g., health vs. economic benefits) or what measures will insure there is no risk to certain values
- In the real world, regulatory science rarely provides this kind of certainty
  - Uncertainties of various kinds are endemic to risk assessment
  - Regulators often have to decide before there is time (or resources) to reduce these uncertainties.

Implications of Deciding Under Uncertainty……

- The assessment of risks and benefits could turn out to be erroneous.
- If you turn out to be wrong, your course of action will sacrifice more of the one than the other.
- It is the classic scientific decision between Type I and Type II errors.
  - In court, is it better to wrongly convict the innocent or wrongly acquit the guilty?
  - In regulating new drugs, is it better to wrongly forego the health benefits of the product or wrongly subject patients to greater harms than anticipated?

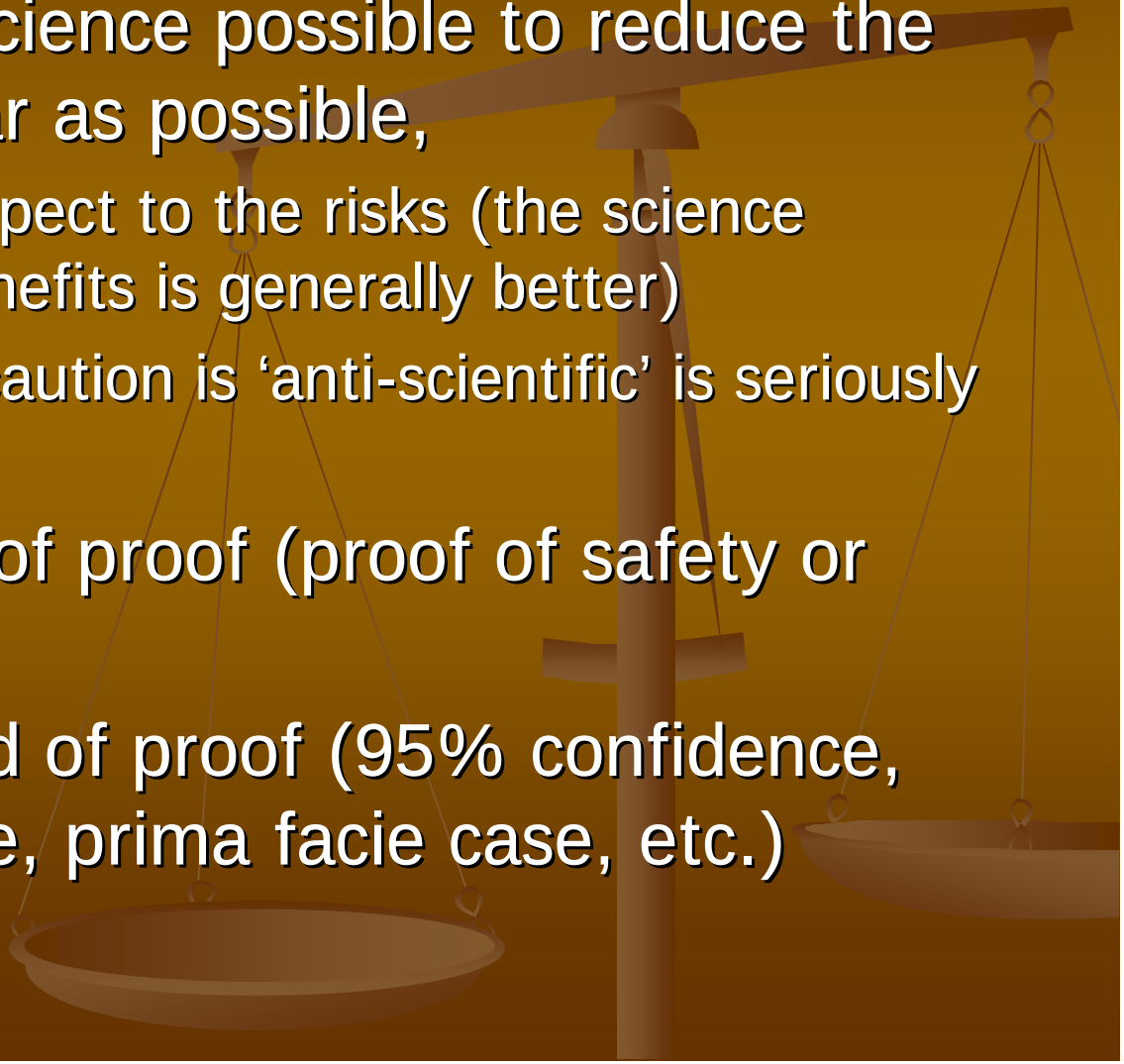


The Point:

- Every regulatory decision under uncertainty will be precautionary about some of the conflicting values and non-precautionary about others.
- The question is: which values deserve precautionary treatment?
  - The intended health, economic, social benefits?
  - The unintended health, economic, social risks?
- Primary Question: To which set of values should a regulatory agency (e.g., Health Canada, CFIA, Environment) give priority of protection?

1. Scientific Elements of Precautionary Regulation

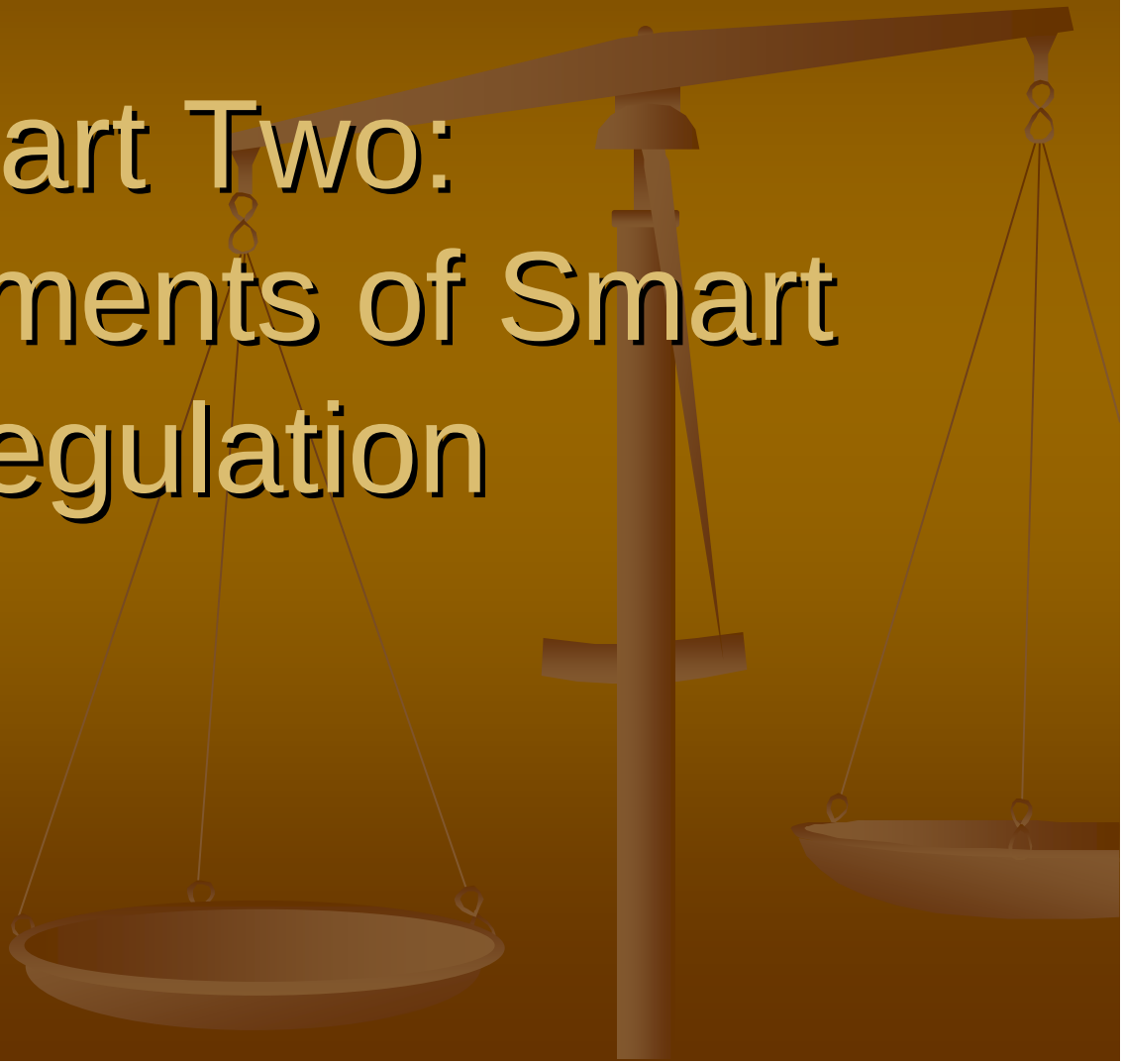
- Getting the best science possible to reduce the uncertainties as far as possible,
  - especially with respect to the risks (the science supporting the benefits is generally better)
  - The idea that precaution is ‘anti-scientific’ is seriously erroneous
- Assigning burden of proof (proof of safety or risk)
- Assigning standard of proof (95% confidence, weight of evidence, prima facie case, etc.)



2. Extra-Scientific Elements of Precaution (Risk Management)

- Assigning the appropriate safety standard
  - Risk/Benefit
  - Cost Effectiveness
  - ALARA
  - Threshold standards (ADI, NOAEL, ‘Natural Background’, etc.)
  - Presumed or Actual Acceptance
  - ‘Zero Risk’
- This list runs roughly from least to most precautionary

Part Two:
The Elements of Smart Regulation



The Primary Aims of ‘Smart Regulation

“Our recommendations are aimed at modernizing the regulatory system to more effectively provide a high level of protection to Canadians, promote the transition to sustainable development and foster an economic climate that promotes innovation and investment.”

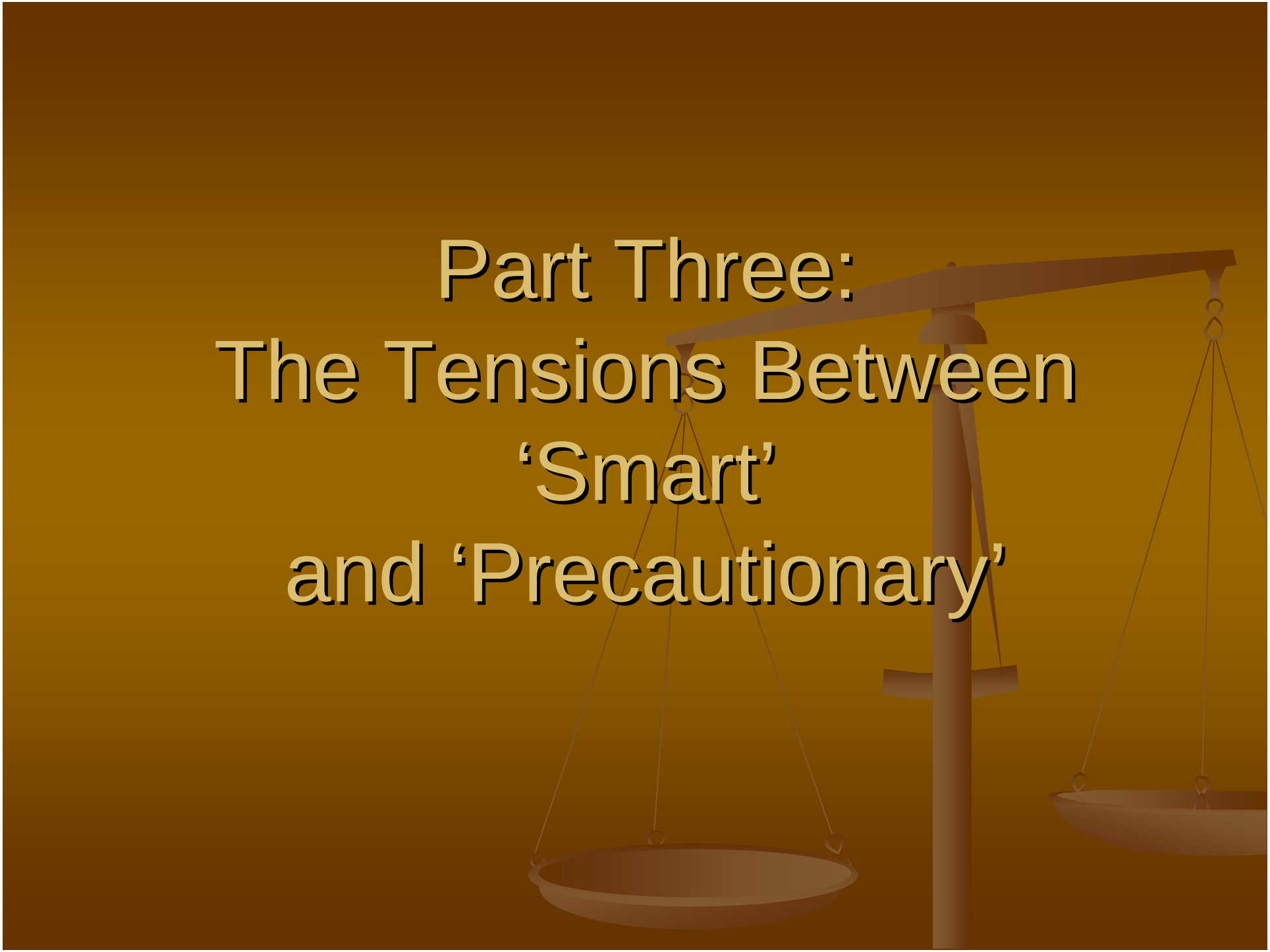
-The External Advisory Committee on Smart Regulation (EACSR)

Basic Principles of Smart Regulation (EACSR)

- EFFECTIVENESS – Regulation must achieve its intended policy objectives and must advance national priorities.
- COST-EFFICIENCY – Regulatory analytical requirements, measures and enforcement should be commensurate with the risks and problems involved.
- TIMELINESS – Regulatory decisions must be provided in a manner that reflects the pace at which new knowledge develops, consumer needs evolve and business now operates.
- TRANSPARENCY – Accessible and open to the public
- ACCOUNTABILITY AND PERFORMANCE – Regulators must account for their performance.

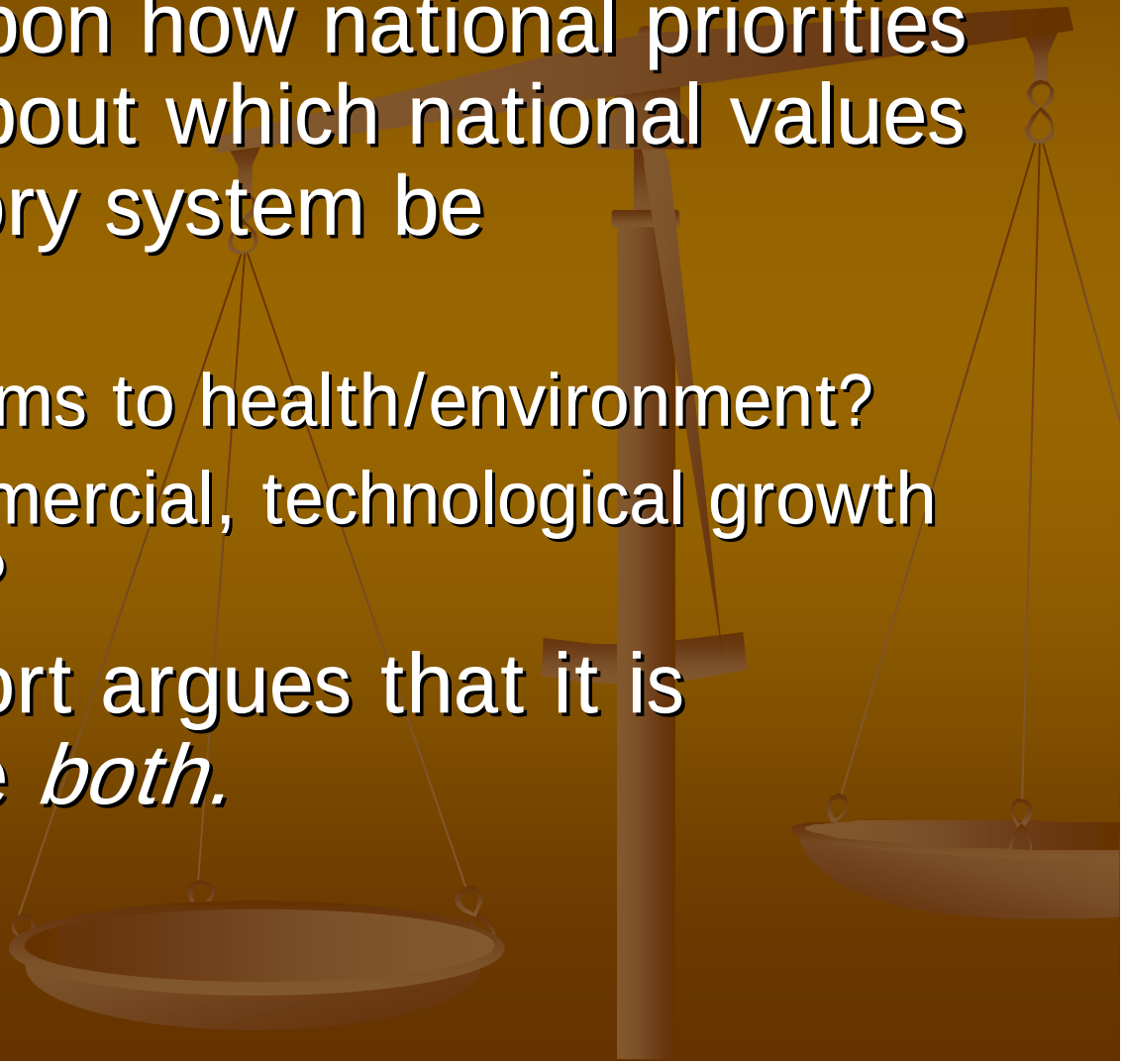
What Will 'Smart Regulation' Change? (EACSR)

- Coordinate Federal & Provincial Regulation
- Harmonize and Share Regulation w/ Trading Partners
- Make Regulatory Processes More Cost-Effective and Timely.
- Change the Risk Management Framework
  - Prioritization
  - Science Based Risk Assessments
  - Adopt "Precautionary Approach"


Part Three:
The Tensions Between
‘Smart’
and ‘Precautionary’

“Effective Advancement of National Priorities”

- This depends upon how national priorities are defined – about which national values will the regulatory system be precautionary’?
  - Unintended harms to health/environment?
  - Economic, commercial, technological growth and innovation?
- The EACSR report argues that it is possible to have *both.*



Cost-Efficiency

- Cost-efficiency means getting the most value at the least cost
  - Here again, the question is, which value will be sought at the least cost?
- If the value is promotion of technological innovation, then this means cutting the regulatory requirements and facilitating ‘innovation’

“Timeliness”

- This is a major objective of Smart Regulation – to reduce the time it takes for an innovator to get a product through the regulatory process.
- Which of the competing values is being given priority by this principle?
  - Is timeliness consistent with the requirement that sufficient science be done to reduce uncertainty to the minimum with respect to health and environmental values?
  - Is timeliness consistent with a high standard of proof (of safety)?

Harmonization & Co-ordination with Trading Partners

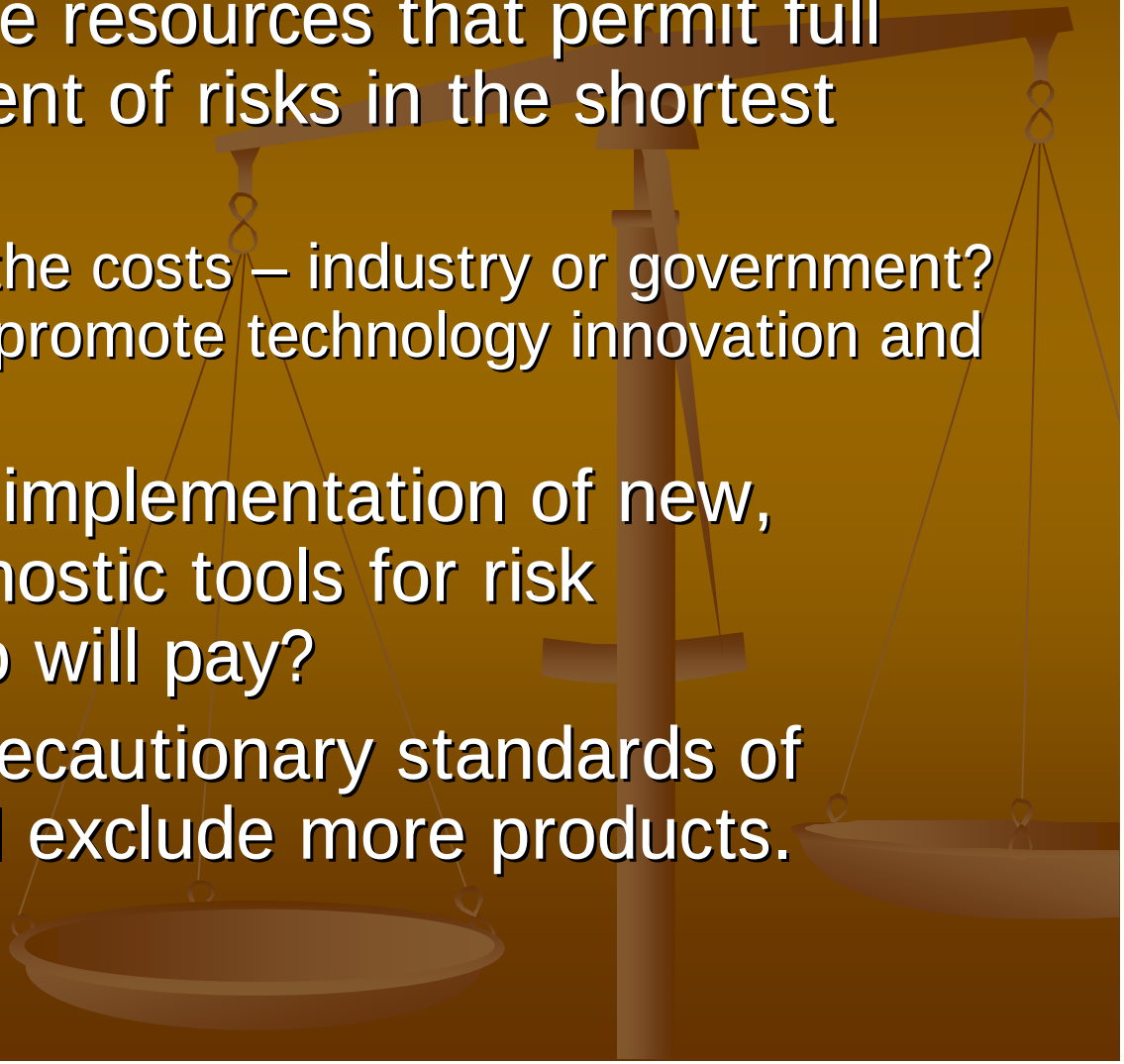
- The obvious questions:
  - Does harmonization of regulatory practices require lowering of precautionary standards?
  - Does acceptance of trading partners' regulatory approvals involve an acceptance of lower precautionary standards?
- These questions can be answered only by looking at the trading partners whose regulatory approvals we accept – What are their value priorities?

Of What Value are Commitments to 'Science-Based Risk Assessment'?

- Usually these commitments are veiled attacks on giving precautionary priority to health and environmental values.
  - 'Don't restrict product approval unless you have a strong scientific basis for doing so.'
  - I.e., 'Give the burden of proof to those who allege risk, demand a high scientific standard of proof, and use a liberal safety standard.
- This approach is NOT precautionary with respect to health and environmental risks.

What Would it Take to Make Regulation both Smart & Precautionary?

- Commitment of the resources that permit full scientific assessment of risks in the shortest period of time.
  - Who should bear the costs – industry or government? If the later, will it promote technology innovation and transfer?
- Development and implementation of new, cutting-edge diagnostic tools for risk assessment? Who will pay?
- Maintenance of precautionary standards of safety – which will exclude more products.



Is Smart Regulation Likely to Meet These Requirements?

What do you think?