Risk Policy: Evidence and Precaution in the USA and Europe

Jonathan B. Wiener
Professor of Law, Environmental Policy and Public Policy, Duke University, USA
University Fellow, Resources for the Future (RFF)
Past President, Society for Risk Analysis (SRA)
Member, IRGC Scientific Council

"Evidence-Based Policies in a World of Uncertainty and Ambiguity"
EuroScience & IRGC session at ESOF
Copenhagen, 24 June 2014

Risk, Uncertainty, Evidence and Precaution

- How can regulation deal with risks when science is incomplete?
  - There is never "complete" science. We are always learning. Sequential decision making under uncertainty. Decide – evaluate – improve decision.
- Can policies succeed if they are not (only) 'evidence-based'?
  - If 'evidence-based' means 'waiting for retrospective evidence'…
  - Yes. Precaution can be successful while we are learning.
    - 1830s: Ignaz Semmelweiss: getting doctors to wash hands. Observed death rates, but lacked germ theory of transmission. Struggle.
    - 1970s: Phasing out CFCs to protect the Ozone layer. 1974 theory.
  - But: best to *combine* precaution and evidence (as both these examples did).
    - "Provisionality" (Eur. Comm'n 2000) Adaptive regulation. Learn, improve.
    - Avoid "risk-risk tradeoffs" (Graham & Wiener 1995).
    - Infections: Semmelweiss – Lister – Pasteur. Soap, antisepsis, antibiotics (saved lives; but risk-risk tradeoff from overuse?)
    - Ozone: CFCs – research – HCFCs – HFCs – climate change (R-R) …

Evidence-based and Social choices

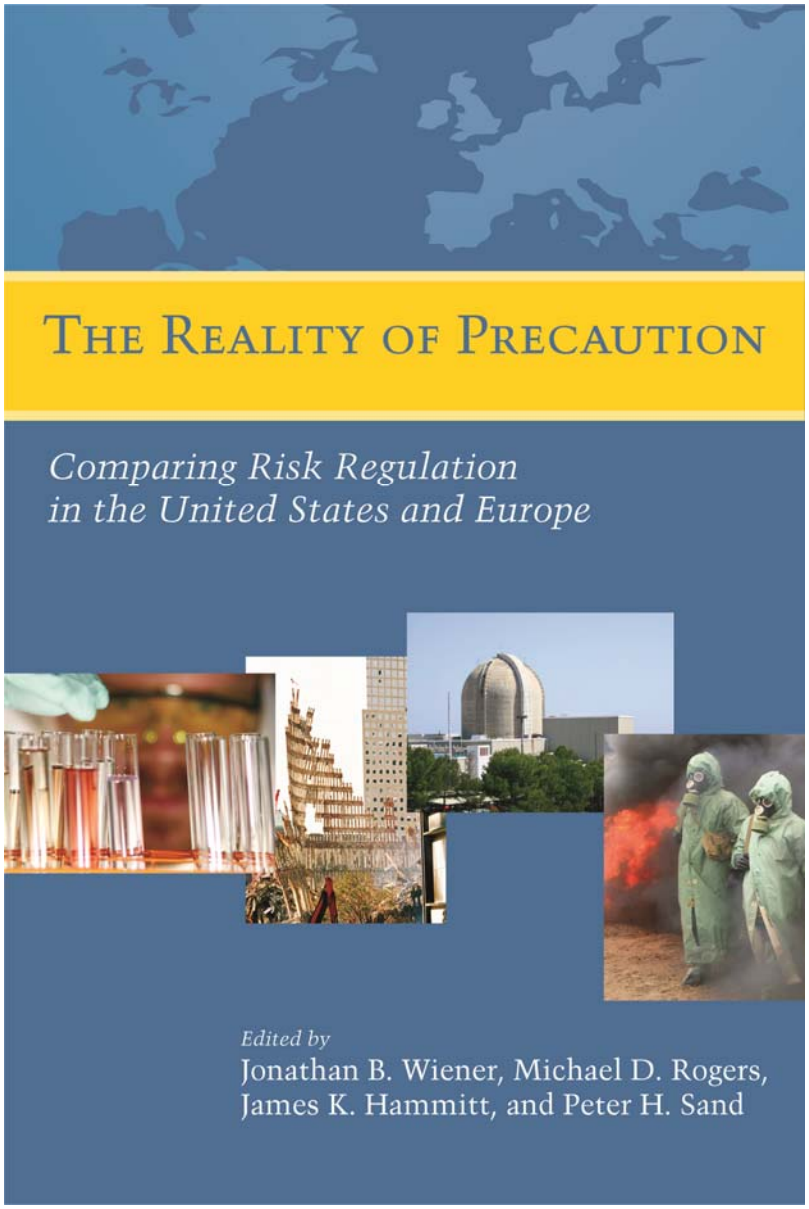
- Can ‘evidence-based’ policy be seen as a way to impose choices on society?
  - No. ***All* policies *reflect* social choices.**
- What happens when societal expectation influences policy?
  - It *always* does. But acting on just fear – neglecting evidence – can be unwise.
  - WMDs, counterterrorism: highly precautionary US policy. False positive? Neglect of risk-risk tradeoffs. (Stern & Wiener 2008)
  - BSE (mad cow): highly US precautionary policy against European blood. False positive? Risk-risk tradeoff: restricts 6-8 % of US blood supply.
  - Air pollution: evidence-based approach (and BCA) = *more* protective.
- Need to *combine* precaution and evidence; need both expert analysis and public input.
  - 1976: US Clean Air Act is a “precautionary” law; can regulate in advance of harm. Plus: much evidence; 5 year reviews.
  - US system: Congress (politics); Agencies (“Notice & Comment” rulemaking); President (and OIRA review); Courts (judicial review).

Comparing regulatory systems:

Has Europe become “more precautionary” and protective than the USA ? Are European standards generally more stringent?

Or are the USA and Europe each *selective* in precaution, as to different risks?

And, are they sharing ideas risk regulation?



(RFF Press/Earthscan/Routledge, 2011)

Divergent cultures: transatlantic stereotypes?

USA

- Risk-taking
- Optimistic about technology
- Individualist
- Skeptical of government
- Adversarial legalism

Europe

- Risk-averse
- Skeptical of technology
- Collectivist
- Favorable toward government
- Informal corporatist

But these are *stereotypes* that don't describe reality:

- Long seen as humorous exaggerations
  - de Beaumarchais, *The Barber of Seville* (1773)
  - Oscar Wilde, *The Canterville Ghost* (1887)
- Incompatible with claims of change over time
  - e.g. claim of 'reversal' from greater US precaution in 1970-90
- Inconsistent with key case studies

Reversal over time: More Precautionary Than Thou ?

"More and More, Europeans Find Fault with US: Wide Range of Events Viewed as Menacing" -- *NY Times*, 9 April 2000, p.A1

"Americans seem to be pragmatic about new ideas and inventions. Europeans tend to worry. … a pervasive technophobia … -- T.R. Reid, *Wash. Post*, 2001

"Precaution is for Europeans" – *NY Times*, April 2003

"Europe is considered fairly risk-averse … America, on the other hand, is often seen as having a strong risk-taking culture" – *The Economist*, 24 January 2004

View espoused by:

- EU officials
- NGOs
- News media
- Scholars

"In the US they believe that if no risks have been proven about a product, it should be allowed. In the EU we believe something should not be authorized if there is a chance of risk."
-- Pascal Lamy, EU Trade Commissioner, 1999

E.g. David Vogel et al. (2000, 2001, 2003, 2012): "Reversal" ("flip-flop") in relative US/EU precaution, 1970-90 vs. after 1990

The Reality of Precaution

Edited by J.B.Wiener, M.D.Rogers, J.K.Hammitt, P.H.Sand

(RFF Press / Earthscan / Routledge, 2011)

I. Introduction

The Rhetoric of Precaution – Wiener

II. Case Studies of Specific Risks

Genetically Modified Foods – Lex & Cantley

Beef Hormones and BSE – Gray et al.

Smoking Tobacco – Blanke

Nuclear Power – Ahearne & Birkhofer

Automobile Emissions – Walsh

Climate and Strat. Ozone – Hammitt

Biodiversity – Saterson

Marine Environment – Freestone

Chemicals – Renn & Elliott

Medical Errors, new drug approval and patient safety – Miller

Terrorism and WMD – Stern & Wiener

III. Information Systems

Information Disclosure – Sand

Risk Analysis Methods – Rogers & Charnley

IV. Quantitative Empirical Analysis of Comparative US and EU Precaution – Swedlow, Hammitt, Wiener, Kall & Zhou

V. Explanations?

Political Systems – Majone

Legal Systems – Bergkamp & Smith

Perceptions and Culture – Weber & Ancker

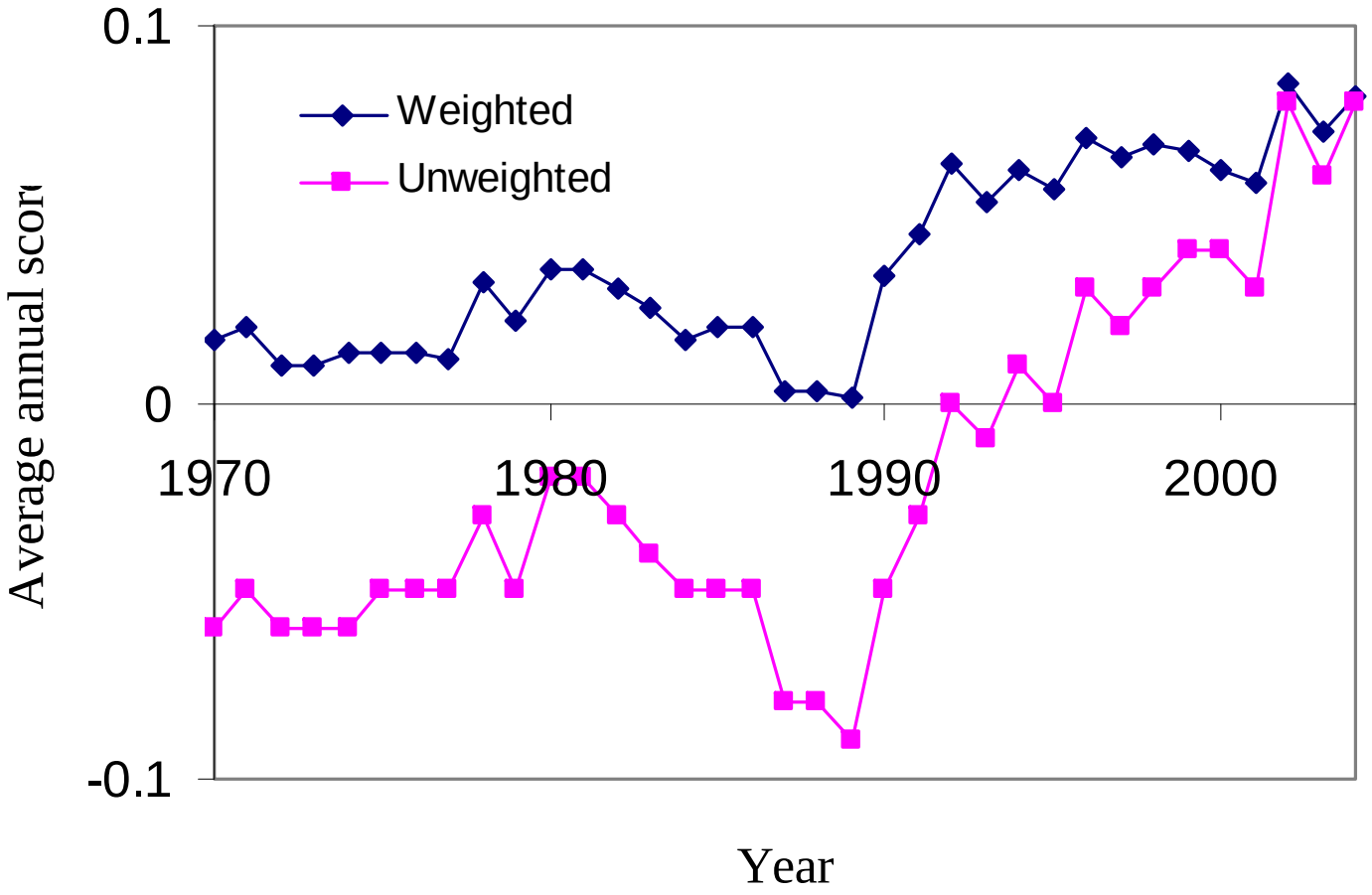
Perceptions and Selection – Sunstein

VI. Conclusions

The Real Pattern of Precaution – Wiener

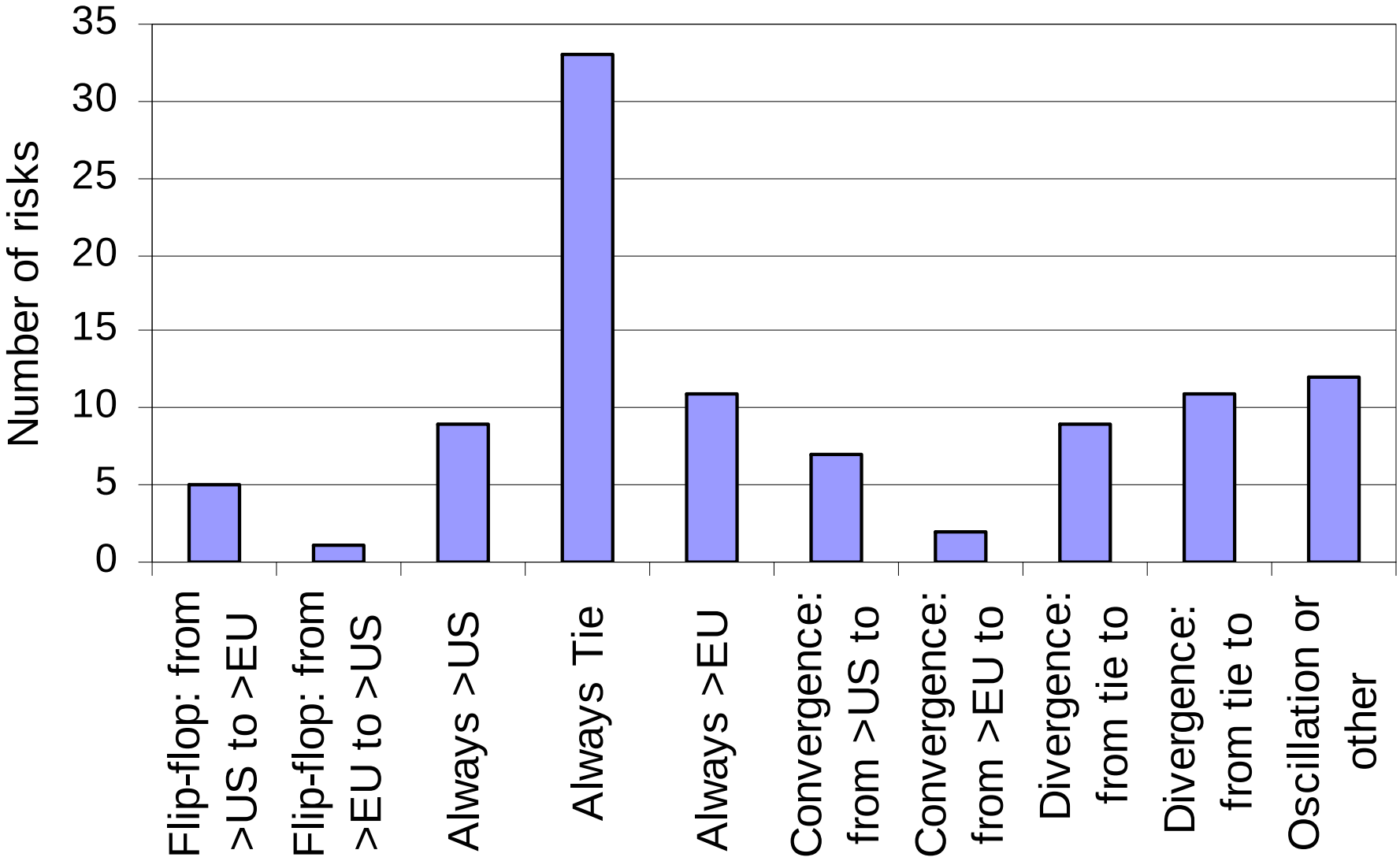
Quantitative analysis of a sample from 2,878 risks

Figure 1. Trends in relative precaution
(all risks)



From: Swedlow et al., chapter 15.

Figure 4. Patterns of Relative Precaution



Summary of Quantitative Sample

- ***Parity***. Overall, no significant US-EU difference.
  - Very slight shift toward relatively more precaution in EU since 1990.
  - But very slight: equivalent to a switch toward greater EU precaution in only 3-6% of sample.

- ***Particularity***. Some divergences on specific risks.
  - Shift toward greater EU precaution: 21 risks
  - Shift toward greater US precaution: 14 risks
  - Always equal: 33 risks
  - EU always more precautionary: 11 risks
  - US always more precautionary: 9 risks

Parity and Particularity: *Selective* Precaution

EU

1970s – 80s:
- **Marine pollution**
- **Guns**

1990s - present:
- **Hormones in Beef, rBST**
- **GM foods / crops**
- **Antibiotics in animal feed**
- **Toxic Chemicals**
- **Climate change**

US

1970s – 80s:
- **New drug approval**
- **Stratospheric Ozone (CFCs)**
- **Nuclear energy**
- **Endangered species**
- **Lead (Pb) in gas/petrol**

1990s - present:
- **Smoking tobacco**
- **Air pollution: Particulate Matter (PM 2.5)**
- **Mad cow: BSE/vCJD in Beef, Blood**
- **Choking Hazards**
- **Terrorism**

Air Pollution: Particulate Matter (PM 2.5)

- **USA: policies restricting PM 2.5 and diesel**
  - **Limit on PM2.5 (annual average): 15 µg/m3, since 1997 (12 µg/m3, after 2020)**
  - **< 3% diesel automobiles**
  - **Annual mortality from PM: ~ 20,000 - 50,000***
- **Europe: policies favoring diesel (in part to reduce CO2)**
  - **Limit on PM2.5 (annual average): 25 µg/m3, after 2015**
  - **> 20% diesel automobiles**
  - **Annual mortality from PM: ~ 150,000 - 370,000***

= simultaneous precaution, against conflicting risks

* Silva, West, et al., *Environ. Res. Ltrs.* (2013); Evans et al., *Environ. Res.* (2012); Anenberg et al., *Environ. Health Perspec.* (2010); European Environ. Agency (2009); Mokdad et al., *JAMA* 291: 1238-45 (2004).

BSE / vCJD (mad cow)

	UK	Europe	USA
Cases	~ 200,000 (1986-)	~ 2,000 (1990-)	~ 3 (deer/elk 2001-? Canada 2003)
British beef ban	No	Temporary (1996-99)	Yes (1989-)
MBM prohibition	Yes (1988)	Yes (1994)	Yes (1997)
SRM prohibition	Yes (1989)	Yes (1997)	No
Beef > 30 months prohibited	Yes (1996)	No	No
Examination at slaughter	No	Yes (2000)	No
Blood donors restricted	No (leukodepletion)	Limited	Yes (= 6-8%) (1999-)

(Source: Gray, Wiener & Rogers, 2010)

Terrorism -- Justifications

- **European Environment Agency, 1/02: “Forestalling disasters usually requires acting before there is strong proof of harm.”**
- **EU Env’t Commissioner Margot Wallstrom, 4/02: "If you smell smoke, you don’t wait until your house is burning down before you tackle the cause.“**
- **NGO advocate of the PP: “Sometimes if we wait for proof it is too late. … If we always wait for scientific certainty, people may suffer and die, and damage to the natural world may be irreversible.”**
- **Pres. Bush at West Point, 6/02: “If we wait for threats to fully materialize, we will have waited too long.”**
- **US National Security Strategy, 9/02: “America will act against such emerging threats before they are fully formed. … The greater the threat, the greater is the risk of inaction — and the more compelling the case for taking anticipatory action to defend ourselves, even if uncertainty remains ...”**
- **(In 2010, the Obama administration revised the NSS to “carefully weigh the costs and risks of action against the costs and risks of inaction.”)**

Terrorism -- Critiques

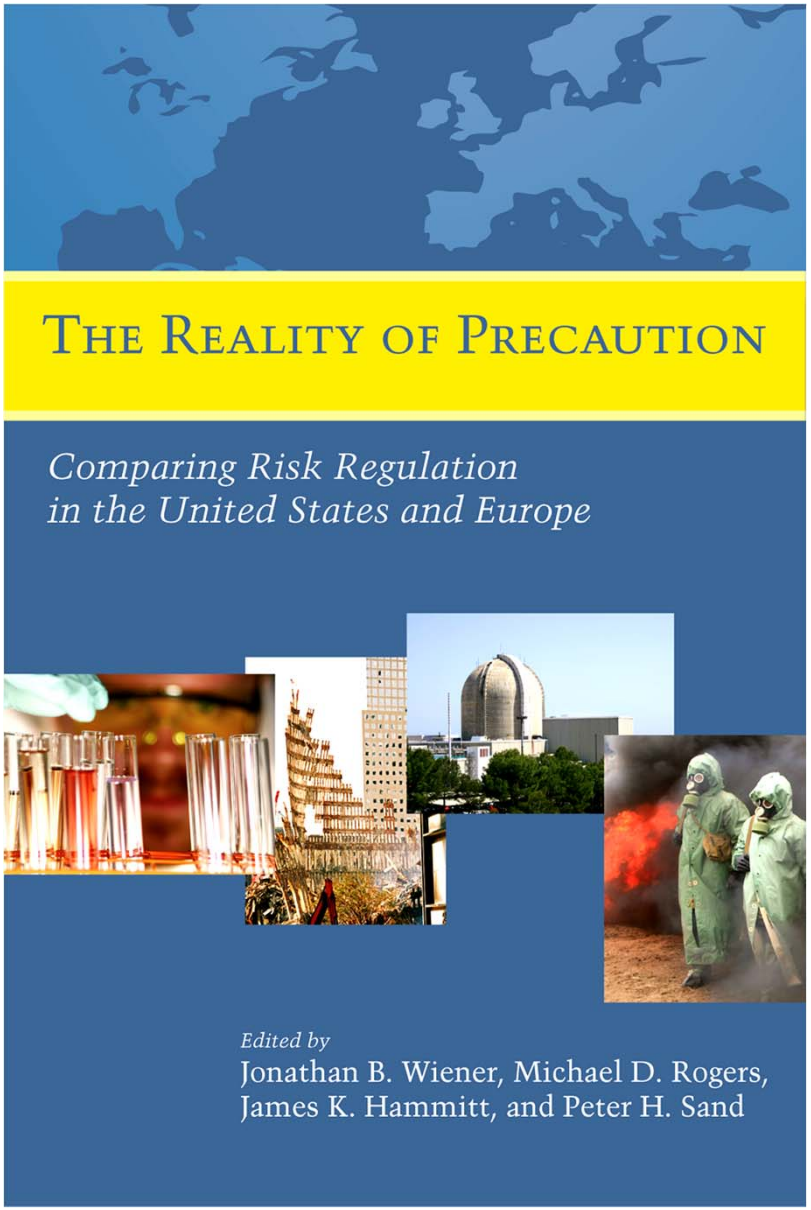
- **US response to EU demands for environmental precaution (e.g. re GMOs): uncertainty warrants no action until more evidence of risk is found.**

- **Joschka Fischer, German Foreign Minister and Green Party leader, 9/02: "To what consequences would military intervention lead? … Are there new and definite findings and facts? Does the threat assessment justify taking a very high risk? … we are full of deep skepticism regarding military action ...”**
- **UN weapons inspector Hans Blix, 2003: “It is clear that the critical thinking we applied led us less astray than did the assertive thinking of the US administration ... We never said there were weapons of mass destruction. What we said was that the Iraqis could not answer all our questions regarding their arsenal. But, for the Bush administration, 'unaccounted for' equaled 'existing.'”**
- **NY Times editorial, 2003: “If intelligence and risk assessment are sketchy -- and when are they not? -- using them as the basis for pre-emptive war poses enormous dangers.”**

Are some societies "more precautionary" than others?

We studied US and Europe, 1970-2010:

- A dozen case studies.
- Quantitative comparison of a random sample from a universe of 2878 risks.
- Explanatory factors.
- Impacts.



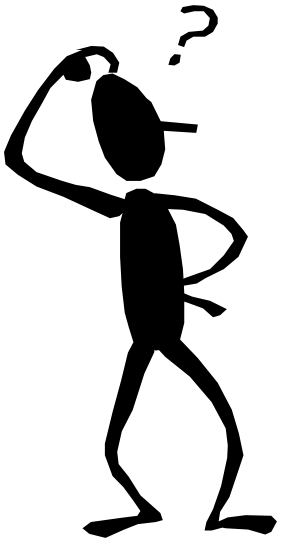
(RFF Press / Earthscan / Routledge, 2011)

Plus symposia in *Reg. & Gov.* (2013) and *EJRR* (2013).

Key findings:

- *Selective* application of precaution, in both Europe and the USA.
- No strong US-EU trend: < 6% shift.
- Not due to broad shifts in public, leaders, BCA. Trade protection, crises.
- Hybridization: much legal borrowing: e.g. PP, Better Reg., Impact Assessment (IA).
- Precaution can yield risk-risk tradeoffs. Need IA, foresight, optimal precaution.

Can we Explain the Pattern of Particularity?



- **Policies well tailored to each risk, BCA ?**
- **Protecting domestic interests (trade, industry, culture) ?**
- **Risk perceptions ?**
  - **cultures of risk-taking, risk-aversion?**
  - **(dis)trust in institutions**
  - **dread of the unfamiliar, unnatural**
  - **“availability” heuristic (recent crises)**
- **Politics (3rd parties e.g. Greens; parliamentary vs SOP) ?**
- **Legal systems ? common law / civil law …**
  - **asymmetric domestic enforcement (US > EU) = US reluctance re PP**
  - **ex post remedies (tort law, US > EU) = PP less urgent in US**
  - **proportionality principle as a limit on PP in EU**
  - **centralized regulatory review in US, now EU**
- **Other ?**
- **Simple US-EU contrasts don’t fit the complex pattern.**
- **Particularity is better explained by selective stimuli, such as the availability heuristic (crisis events).** But some effects are distant, e.g. BSE and US policy, or Fukushima and German policy.

Implications of *The Reality of Precaution*

- **Reality: complex pattern of Parity and Particularity.**
  - **Neither EU nor USA is *generally* more precautionary than the other.**
  - **Must study wide array of cases (not just rhetoric, or recent visible examples).**
  - **Selective application: Precautionary particularity, not principle.**
  - **Comparing legal "systems/origins/families" overlooks complex variation by issues, laws, institutions, context.**
- **Multiple explanations for the observed complex pattern**
  - **Including: trade protectionism, public perceptions, crisis events**
- **Actual precautionary regulation is often moderated.**
  - **False negatives, but also False positives, Costs, Risk-Risk tradeoffs**
  - **Need *both* precaution and 'evidence-based'. Learning, updating.**
  - **Toward optimal (not maximal) precaution**
- **Move to "Better Regulation" in both the USA and EU**
  - **Transatlantic consensus: Regulatory Impact Assessment to support Executive oversight**
  - **Both Precaution and RIA are forms of foresight**
- **Diffusion, borrowing: increasingly interwoven "hybridization" of regulatory systems (more than convergence, divergence, reversal).**
  *** Opportunity for learning through comparison and exchange.**

Learning from the USA and Europe: Toward "Even Better Regulation"

- Match the IA system to the structure of governance
- Not just Administrative Cost.
- Integrated Impact Assessment of full portfolio effects.
- Use RIA more broadly and evenhandedly:
  - Cover legislation (as in EU) as well as rulemaking (as in USA). An office in Congress?
  - Use "Warm analysis": proportionate analysis, qualitative too, not narrow quantification
  - "Prompt" good policies ("Yes") as well as discourage/revise bad policies ("No")
  - Use IA more widely: not only for health & environmental regulation but also for financial, homeland security, trade, and other regulations; decisions not to regulate, deregulation, and regulatory moratoria; as well as for subsidies, public projects, forest management, military procurement, foreign policy, etc.
  - Use Risk-Risk Analysis as well as (or as part of) BCA – to evaluate the full portfolio effects of policies in a multi-risk world – both ancillary harms and ancillary benefits
  - Ex post evaluations of ex ante IAs: to revise policies, and to improve ex ante RIA methods

- Learning from variation: over time, across risks, across agencies, across countries. Comparative observation, and purposive experiments: toward a *global policy laboratory*.

Key publications:

- Jonathan B. Wiener, "The Politics of Precaution, and the Reality," 7 *Regulation and Governance* 258-265 (2013).
- Jonathan B. Wiener, et. al., "Better Ways to Study Regulatory Elephants," 2/2013 *European Journal of Risk Regulation* 311-319 (2013).
- Jonathan B. Wiener, Michael D. Rogers, James K. Hammitt, and Peter H. Sand, eds., *The Reality of Precaution: Comparing Risk Regulation in the United States and Europe* (RFF Press/Earthscan/Routledge, 2011)
- Jessica Stern & Jonathan B. Wiener, "Precaution Against Terrorism," in *Managing Strategic Surprise: Lessons from Risk Management and Risk Assessment*, ch. 5 (Paul Bracken, David Gordon & Ian Bremmer eds., Cambridge Univ. Press, 2008)
- Jonathan B. Wiener, "Better Regulation in Europe," 59 *Current Legal Problems* 447-518 (2006).
- Jonathan B. Wiener, "Whose Precaution After All ? A Comment on the Comparison and Evolution of Risk Regulatory Systems," 13 *Duke Journal of Comparative & International Law* 207-262 (2003).
- Jonathan B. Wiener, "Precaution in a Multi-Risk World," in *Human and Ecological Risk Assessment: Theory and Practice* 1509-1531 (Dennis D. Paustenbach ed., 2002)
- Jonathan B. Wiener & Michael D. Rogers, "Comparing Precaution in the United States and Europe," 5 *Journal of Risk Research* 317-349 (2002).
- John D. Graham & Jonathan B. Wiener, eds., *Risk vs. Risk: Tradeoffs in Protecting Health and the Environment* (Harvard University Press, 1995)

Thank you.

www.law.duke.edu/fac/wiener