Learning from Research about Risk Regulation

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Key themes of the talk

- What have we learned about risk and risk regulation?
- What can we learn?

  - Multiplicity
  - Precaution
  - Variation
  - Learning

Risk

- Combination of probability and impact: p(*I*) . And: valuation, hence perception, culture, context.
- Risk assessment & management: essential to survival (Peter Bernstein)
- Foresight – to envision scenarios and plan ahead: special to humans (Gilbert & Wilson – but "prospection" is anchored by memory)
- Perceptions and decisions: heuristics, errors, biases (Kahneman & Tversky, Slovic, Ariely, et al.)
- Risks to others: externalities, free riding (market failures)
  - need rules or norms to internalize externalities, reduce risk
- Institutions: can reduce risks via collective action, expertise, deliberation
  - but also may induce costs, ancillary risks, dysfunctions (gov't failure)
  - need to minimize sum of errors, i.e. reduce overall risk

Declining risks, but rising concerns?

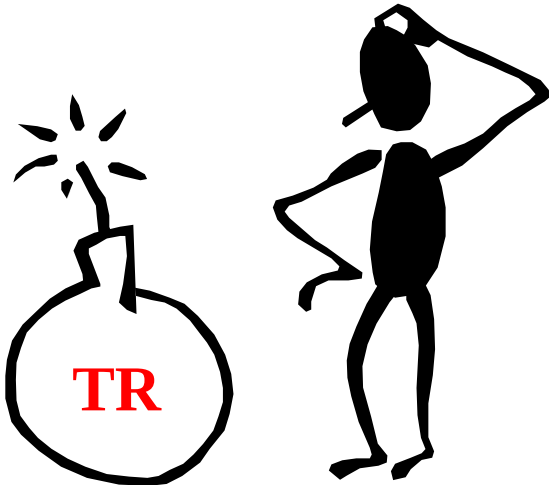
- Increasing human longevity – decreasing risks to human health over time
- Why? Possibilities:
  - Science & technology. Better detection of risks, and better solutions
  - Prosperity. Better nutrition, shelter, sanitation, health care, etc.; and increasing demand for regulatory policies ("EKC")
  - Regulation. May reduce risks (but may also yield costs, risks, etc.)
- Increasing public concern about risks?
- Why? Possibilities:
  - Science = enhanced detection of risks
  - New technology = emerging risks (but also new benefits)
  - Prosperity = increasing demand for health and safety
  - Underaddressed risks (e.g. climate, financial, bacterial)
  - Increasing interconnectedness = wider & faster propagation
  - Greater awareness – news, internet, "availability," outcry
  - Greater longevity itself: longer time horizon of concern
  - Decreasing risk itself: risk salience perceived *relative* to baseline
  - Regulation itself: may spur new concern; new ancillary risks; distrust

Risk Regulation:
in many domains; fragmentation

Health, Safety, Environment, Security … e.g.:

- Public health, disease
- Food & agriculture
- Air
- Water
- Chemicals, pesticides
- Consumer products
- Drugs, cosmetics, tobacco
- Medical safety
- Workplace safety, health
- Transport, traffic, automobiles, aviation, shipping
- Infrastructure, buildings, roads, bridges, tunnels
- Energy, coal, oil, gas, nuclear, hydro, renewables, transmission
- Natural disasters, earthquakes, storms, floods, tornadoes
- Climate
- Financial services
- Terrorism, homeland security
- Extreme risks, catastrophes

Traditional Approach: one Target Risk (TR)

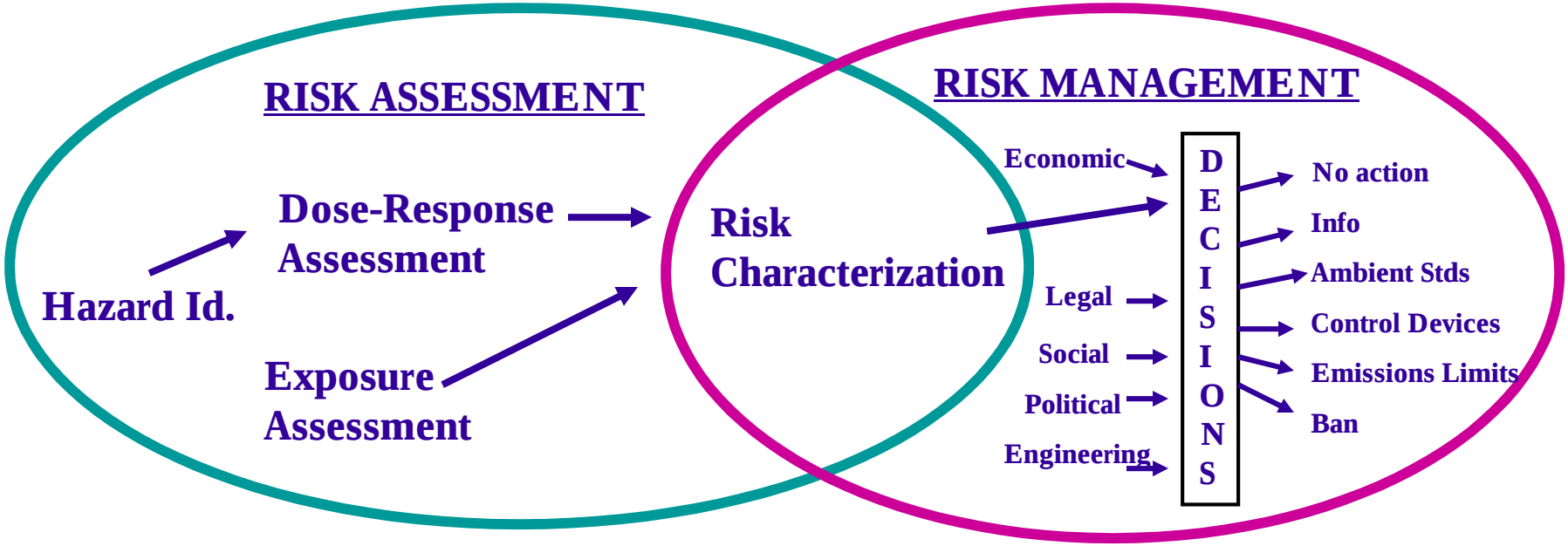


Key questions in risk analysis of the TR

1. How serious is the risk? Risk Assessment (RA): *Forecasting* of probability, impact, uncertainty.
2. What should be done about the risk? Risk Management (RM): *Policy making* including comparing costs, benefits, uncertainties, etc. of alternative policy options.

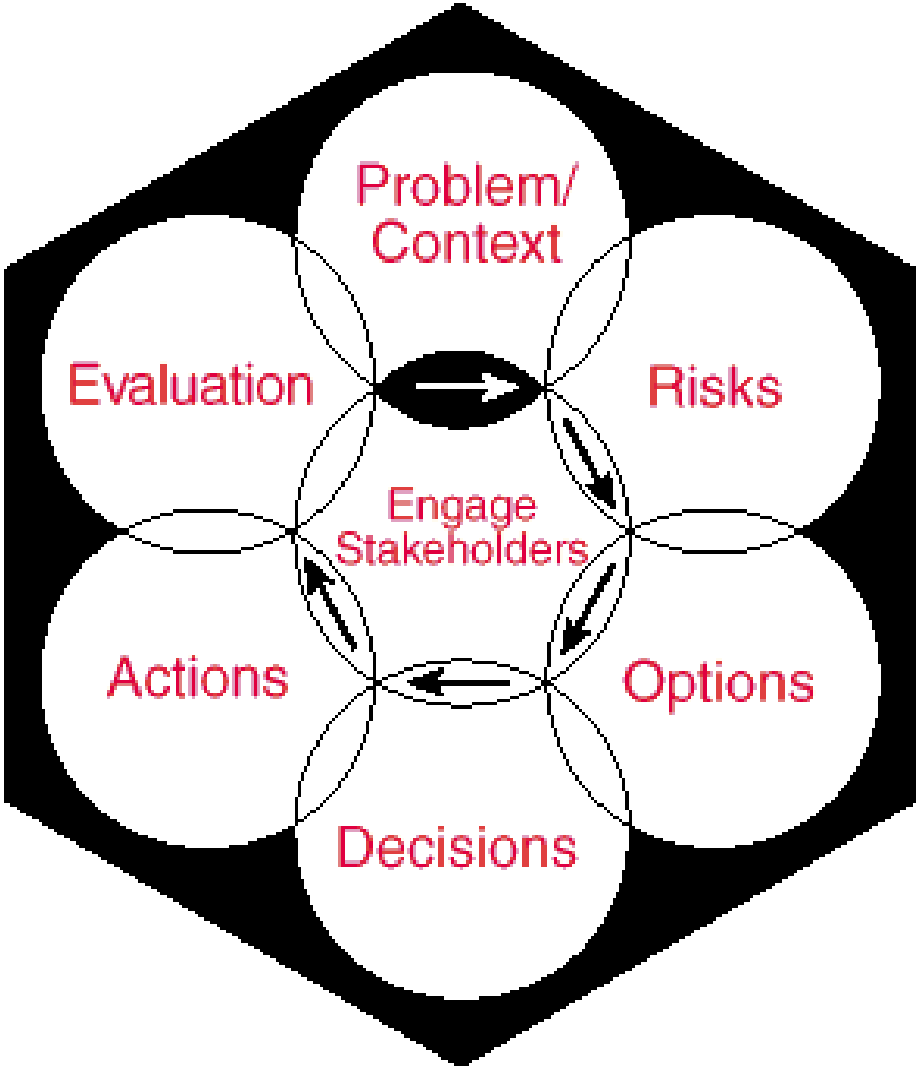
3. [[How well will (or did) the policy work? Impact assessment (ex ante, ex post), Review and Evaluation. *Oversight, learning, updating.*]]

Risk policy process, 1983



(Source: US National Academy of Sciences, *Risk Assessment in the Federal Government*, 1983 (the "Red Book"))

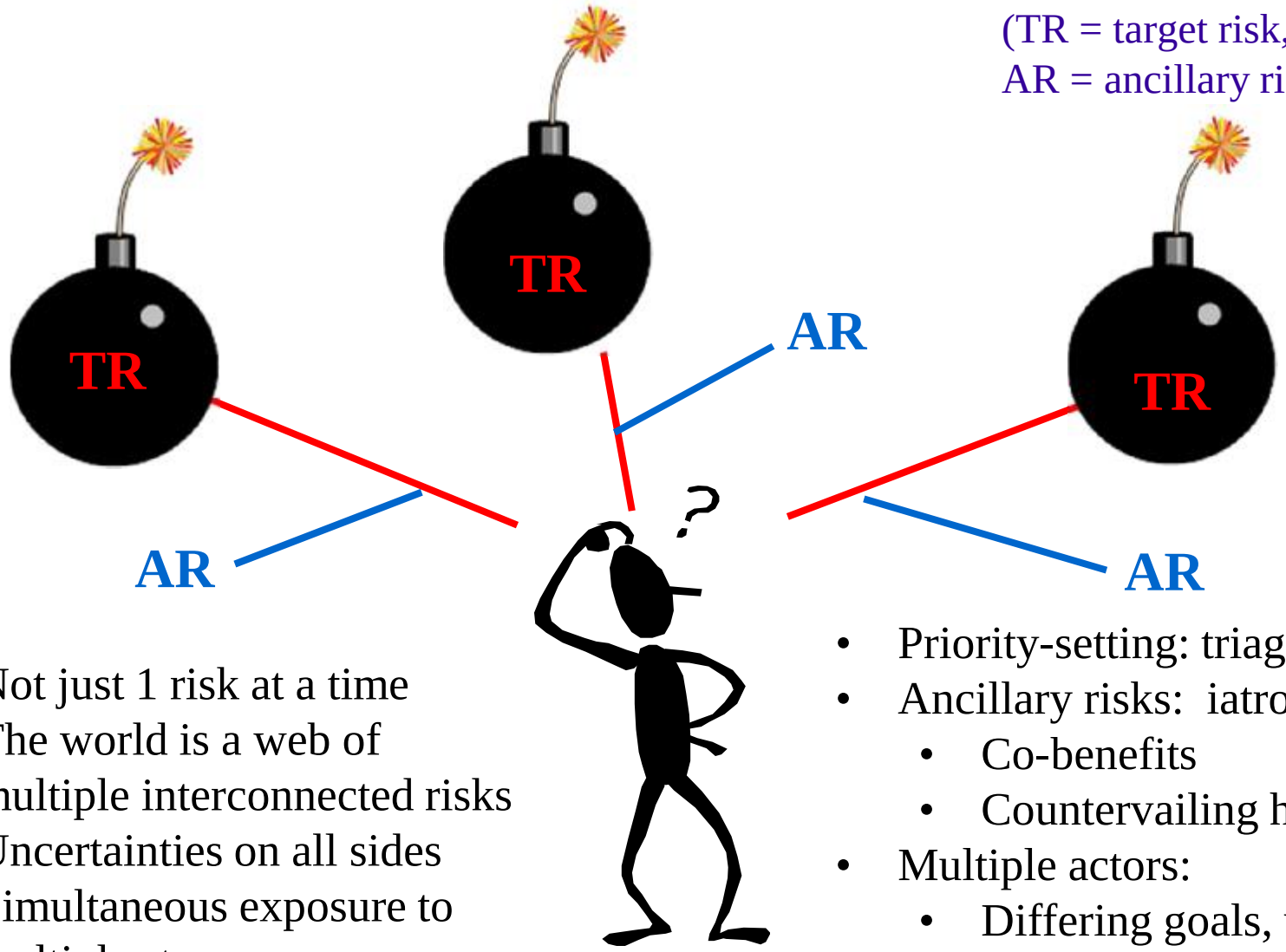
Risk policy cycle, 1997



(Source: US Presidential/Congressional Commission on Risk Assessment and Risk Management, Final Report, Volume 1 (1997))

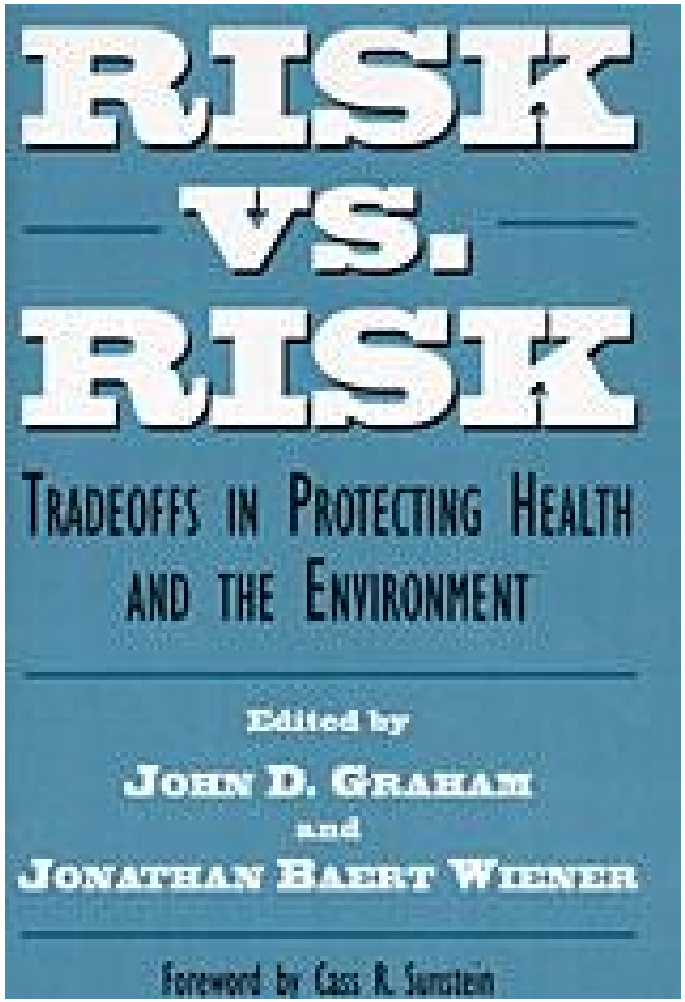
Reality: Multiple Risks

(TR = target risk,
AR = ancillary risk)



- Not just 1 risk at a time
- The world is a web of multiple interconnected risks
- Uncertainties on all sides
- Simultaneous exposure to multiple stressors

- Priority-setting: triage
- Ancillary risks: iatrogenic
  - Co-benefits
  - Countervailing harms
- Multiple actors:
  - Differing goals, values
  - Free riding
  - Fragmentation



(Harvard University Press, 1995)

Risk-Risk: through history and across disciplines

- **Odysseus confronts Scylla vs. Charybdis**
- **Medicine: side effects (iatrogenic injury)**
  - **Hippocrates, 400 B.C.: *"First, do no harm"* (too strict?)**
  - **Ignatz Semmelweiss, 1840s: exhorts doctors to *wash their hands***
  - **Joseph Lister, 1860s: *antisepsis* for surgery**
- **Ecology: interconnectedness**
  - **John Muir, 1869: *"When we try to pick out any one thing, we find it hitched to everything else in the universe."***
- **Economics: externalities**
  - **A.C. Pigou, 1920: *Harms of decisions that neglect full social impacts***
- **Systems analysis**
  - **Applied to policy: Lester Lave, *The Strategy of Social Regulation*, 1981**
- **Impact assessment: *Consider impacts before acting***
  - **Environmental IA, Regulatory IA. US EIA 1969, RIA 1978/1981/1993/2003…**
- **Military strategy: Collateral damage, blowback**
  - **Barbara Tuchman: *The March of Folly***

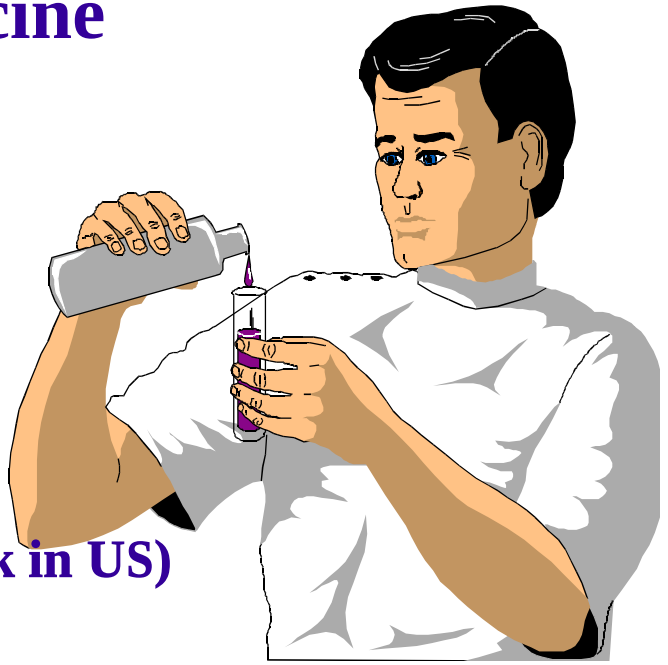
Risk-Risk: an emerging regulatory tool

- Chauncey Starr & Chris Whipple, *Risks of Risk Decisions*, 1980
- Lester Lave, *The Strategy of Social Regulation*, 1981
- Martin Janicke, *State Failure*, 1990
- Daniel Patrick Moynihan, *Iatrogenic Government*, 1993
- Stephen Breyer, *Breaking the Vicious Circle*, 1993
- John Graham & Jonathan Wiener, *Risk vs. Risk*, 1995
- Cass Sunstein, *Health-Health Tradeoffs*, 1996
- Jonathan Wiener, *Managing the Iatrogenic Risks of Risk Management*, 1998
- Jonathan Wiener, *Precaution in a Multirisk World*, 2002
- OMB Circular A-4, section on "Ancillary Impacts," 2003
- Richard Revesz & Michael Livermore, *Retaking Rationality*, 2008
- Graham & Wiener debate with Hansen, Krauss & Tickner in JRR, 2008
- World Bank, *World Development Report 2014: Managing Rusk for Development* (October 2013)

Key points:

- Governments are endogenous, imperfect institutions (as are markets)
- We live in a complex web of multiple interconnected risks
- Policy interventions can both reduce risks and create risks

Insights from seeing Regulation as Medicine



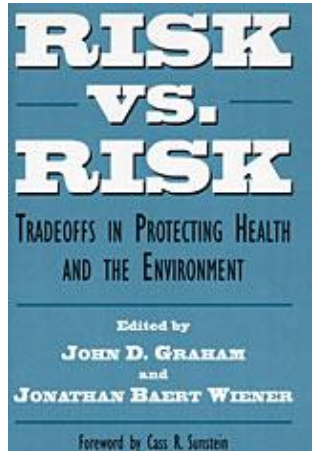
- Society as patient, Risk as ailment,
  Regulation as therapy

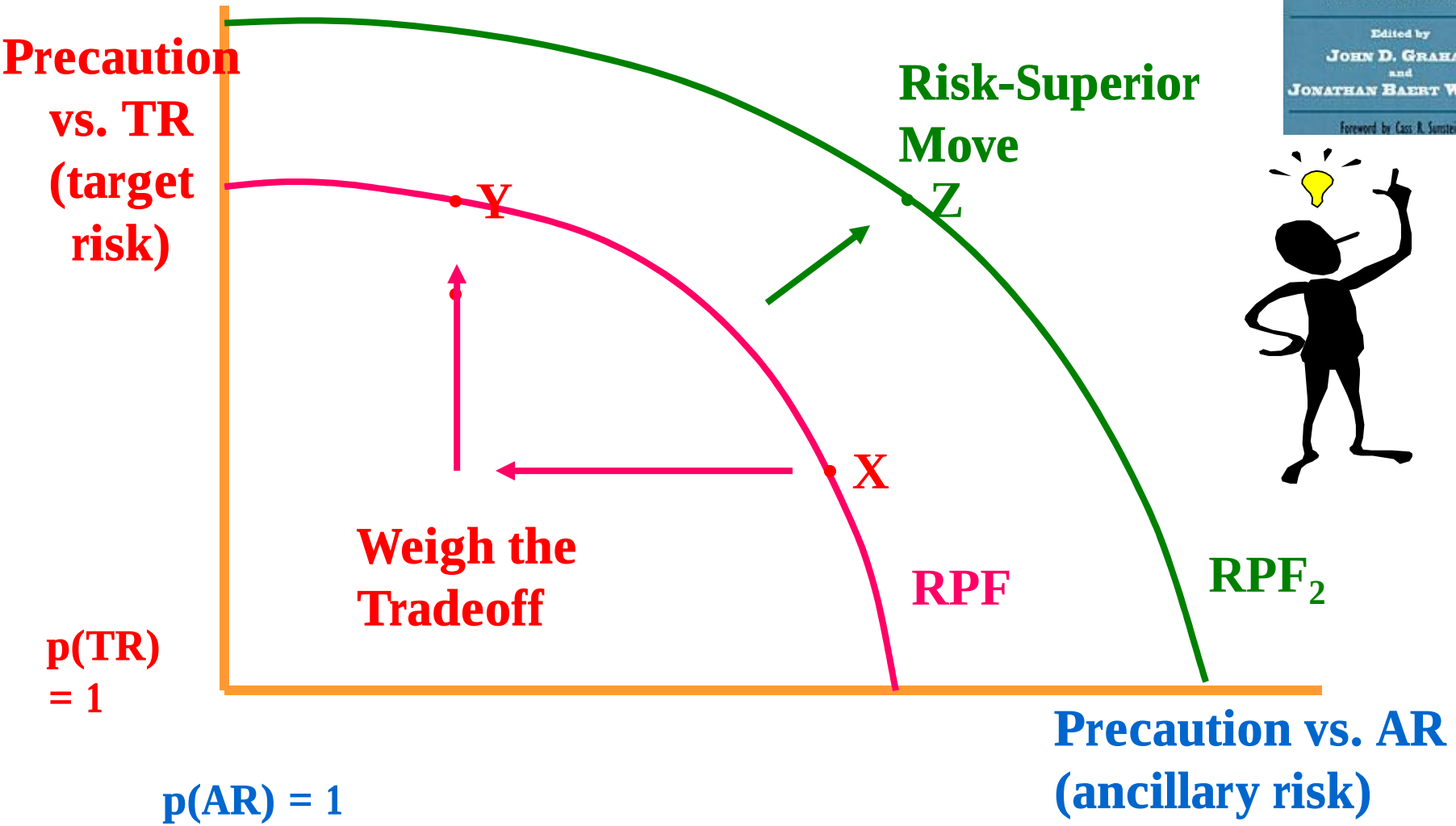
- Triage: priority among risks
- Iatrogenesis: therapy can both heal & harm
  - Aspirin, surgery, vaccines . . .
  - Iatrogenic risks are real risks (IOM: ~100k in US)

- "Treat the whole patient" – the full "system."
  - "Full portfolio impact assessment"
  - "Council of Risk Analysts," "National Risk Board"

- "Risk-superior moves" to reduce multiple risks in concert
  - Confronting R-R spurs innovation (toward *better* regulation)
  - e.g. hand washing, antisepsis, smart airbags, multi-gas climate policy

RTA: Risk-Risk Tradeoffs and Risk-Superior Moves





Risk-Risk Tradeoffs are Pervasive

Intervention	TR	CR	(Risk-superior option?)
• Aspirin	Head	Stomach	(Acetaminophen?)
• Toothpaste	Tooth decay	Fluoride poisoning	(warning label)
• Vaccines	Illnesses	Side effects	
• Hospitals, surgery	Illnesses	Iatrogenic illnesses	(antisepsis…)
• Mammograms, PSA	Cancer	Fear; unnec. surgery; other cancers	
• Antibiotics	Infections	Resistant bacteria	
• Chlorinate H_2O	Pathogens	Carcinogens	(Ozonation?)
• Ban DDT	Wildlife	Malaria	(IRS; vaccine; GM)
• Airbags in cars	Adults	Kids	(Kids in back; smart airbags)
• Reduce trop. O_3	Lungs	Skin / UV	
• Ban asbestos	Lungs	Highway crashes	(copper brakes?)
• Reduce air pollution	Public	Workers inside factories	(EPA-OSHA)
• Waste cleanups	Public	Workers at cleanup sites	
• Suppress forest fires	Some fires	Worse fires	
• Control floods	Some floods	Worse floods	
• Facility risk disclosure	Accidents	Terrorism	(EPA-FBI)
• Rescue banks (TBTF)	Market panic	Moral hazard	(Dodd-Frank?)

Risk-Risk Tradeoffs on all sides

Intervention	TR	CR (risk-superior move?)
• NH_3 to CFCs (1930s)	Toxicity	Ozone depletion
• CFCs to HFCs (1990s)	Ozone depletion	Climate change
• Coal to Gas	CO_2	CH_4 (= should cover all GHGs)
• Coal to Shale Gas	Air pollution	Water pollution; CH_4
• Ban nuclear power	Waste; meltdown	Coal = air pollution; CO_2
• MTBE	Air pollution	Water pollution
• Diesel fuels	CO_2	PM
• Biofuels (corn ethanol)	CO_2 ; oil imports	N_2O; forests CO_2; food prices
• CFL lightbulbs	CO_2	Hg (replace with LED bulbs?)
• CCS	CO_2	Water pollution; seismic
• Geoengineering	Warming	Cooling; ozone depletion; rebound
• Butter to margarine	Saturated fat	Trans-fat (now being banned…)
• Ban foreign blood	BSE/vCJD	Blood shortage
• Feed soy to cattle	BSE/vCJD	Deforestation
• Police chases	Suspects	Bystanders
• War on Drugs	Drug use	Violence
• War on Terror	Terrorism	Terrorism; civilians; privacy; highways

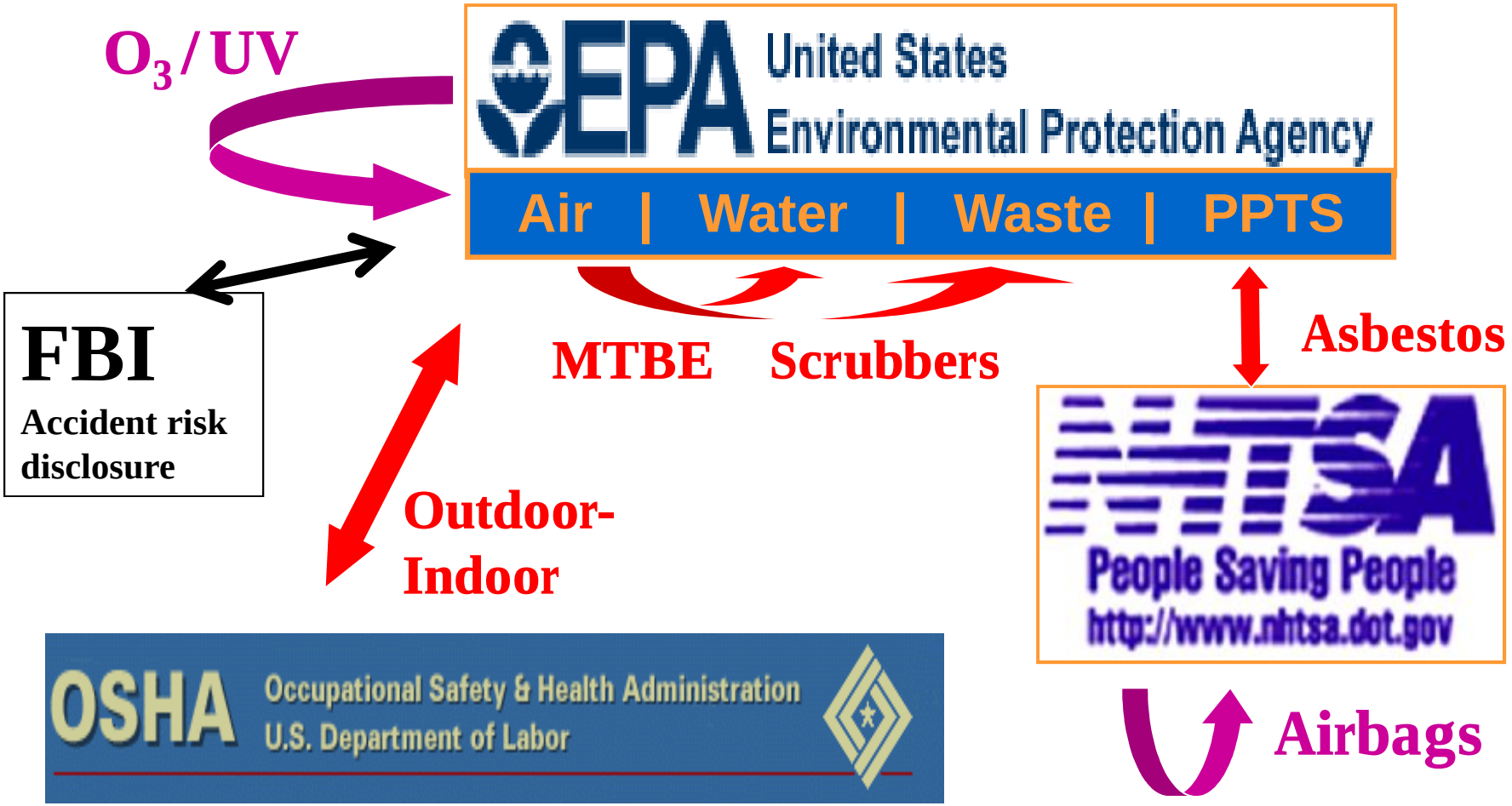
Toward Full Portfolio Impact Analysis

- **Simple, single-risk approaches yield errors**
  - **“Better safe than sorry” vs. “Cure is worse than the disease”**
- **Real world is complex, interconnected, multi-risk web**
  - **Confront & weigh the portfolio of Risk-Risk tradeoffs (1, 2, … n)**
    - **Both ancillary countervailing risks (CRs) and ancillary co-benefits (ABs)**
    - **Differences in type, timing, population, etc. = challenge of comparing**
    - **Seek “Risk-Superior” moves**
  - **PP: Max(ΔTR)**
    - **unless qualified by “cost-effective” or “proportionate”**
  - **BCA: Max(ΔTR - Cost)**
    - **can worsen risk-risk tradeoffs, if TR and cost are narrowly defined**
  - **RTA: Max(ΔTR – ΔCR)**
    - **= reduce overall risk**
  - **Full portfolio: Max(ΔTR – ΔCR + ΔAB - Cost) (… all important impacts)**
  - **But, increases costs of deliberation. How many ripples to assess? …**

Optimal Portfolio Analysis: How Many Ripples?

- **Ideally, consider "full risk portfolio"**
  - **Target Risk (TR), Countervailing Risks (CR), Ancillary Benefits (AB).**
  - **Toward "general equilibrium" analysis of benefits side.**
- **But: risks of delay, "paralysis by analysis."**
  - **Still, full portfolio analysis can (i) improve decision outcomes (reduce overall risk); (ii) avoid problems & backlash later (reduce overall delay); and (iii) yield more comprehensive regulation (e.g. multipollutant, multirisk).**
- **Some ancillary impacts are more important than others**
  - **Some CRs are overstated, or false positives (as are some TRs).**
  - **CRs deserve more attention: (i) as TRs are reduced, i.e. as society grows safer; and (ii) where CR victims are neglected (omitted voice)**
  - **CR can affect decision even if CR < TR**
  - **Analyze CR up to point when MB of expected improvement in decision = MC of deliberation; or, max(VOI-COI)**

Why do Risk-Risk Tradeoffs Occur?



Why do Risk-Risk Tradeoffs Occur? Causes

- **Like private firms, regulatory agencies have incentives to externalize harms outside their domains / constituencies**
  - **Hence neglect of countervailing risk increases may be more worrisome than neglect of co-benefit risk decreases**
  - **But some R-R tradeoffs are within one domain**
  - **Regulators' incentives are not the same as private firms' incentives**
- **Cross-Domain:**
  - **Fragmentation; bounded specialization**
- **Within-Domain:**
  - **Deliberation cost**
  - **Especially after a crisis: hasty policy design**
- **Omitted voice; democratic dysfunction**
- **Cognitive heuristics – e.g. 'availability,' 'mass numbing'**

- **Solutions? Analytic. Institutional.**

Progress on Risk-Risk Tradeoffs

- Medical care
  - Studies of patient outcomes. Checklists to avoid surgical errors. Computerized prescriptions with clear spelling, patient information, and drug-drug interactions.
- Automobile highway safety
  - Airbags; smart airbags; kids in back; surround sensors; self-braking/driving…
- Climate
  - Multi-gas scope in FCCC, Kyoto Protocol, EPA policies, etc.
  - FCCC art. 4(1)(f) calls for RTA: "employ appropriate methods, for example impact assessments … with a view to minimizing adverse effects on the economy, on public health and on the quality of the environment, of projects or measures undertaken … to mitigate or adapt to climate change"
  - US Clean Air Act sec. 108: RTA of pollutants (*Amer. Trucking*, DC Cir. 1999)
  - US Clean Air Act sec. 612: RTA of CFC-substitutes
  - IPCC AR5 WGIII: attention to ancillary risks and co-benefits
  - Research on multiple effects of Geoengineering
- Terrorism
  - Integration of diverse agencies into Dept. Homeland Security and Dir. Nat'l Intel.
  - Bush (2002) National Security Strategy applied PP (preemptive action despite uncertainty). Obama (2010) added: "carefully weigh the costs and risks of action against the costs and risks of inaction."

Solutions for governing risk-risk tradeoffs? Analysis and Institutions

- Impact Assessment (IA) – growing application. How broad?
  - EIA (Environmental Impact Assessment) – widely applied
  - RIA: US Executive Orders (Carter 1978, Reagan 1981, Clinton 1993, Obama …)
    - US OMB Circular A-4 (Bush, 2003): section on Ancillary Impacts
  - EU Impact Assessment Guidelines (2006, 2009, …)
- Inter-agency collaboration on cross-domain risks
  - EPA-OSHA on air toxics. EPA-FBI on disclosure of chemical accident risks.
  - Merging agencies? E.g. after 9/11: DHS, DNI. Helpful?
- Needed / challenges:
  - Integrated analysis – optimal ripples? And, assembling diverse expertise.
  - Integrated structure – but too large, clumsy? Specialization vs. integration.
  - Recursive loop from RA (of TRs), to RM, back to RA (of ARs), to full RM.
  - National and international "outcomes studies" to test full portfolio impacts.
  - "National Risk Boards" (World Bank WDR 2014, citing RvR 1995).
  - International learning, diffusion, cooperation (Wiener 2013).
- Toward a holistic culture of complex risk systems

Risk and Precaution

- Normative
  - Does risk analysis undesirably delay precaution?
  - Does precaution induce undesirable risk-risk tradeoffs?
  - Toward optimal precaution
- Descriptive / Comparative
  - Do countries differ in their degree of precaution?
  - E.g., USA vs. EU
  - How and Why?
- Can we learn?

Precaution: Normative

- Precaution may prevent serious harm
  - If irreversible or catastrophic, then waiting for more evidence, or ex post liability, may be inadequate
  - Concern re false negatives (neglected risks)
- Precaution may induce harms
  - Costly; inhibit innovation (of new technology that could reduce risks)
  - False positives (false alarms) (may yield complacency about true alarms)
  - Countervailing risks (may also be irreversible, catastrophic)
- Wait & research; or Act & research
  - Consider option value of flexibility to adapt to learning
  - Uncertainty implies high value of learning
- "Precautionary Principle" moderated in practice
  - European Commission: includes CBA
  - French Environment Charter: "provisional and proportionate"

Precautionary Principle and Risk-Risk

- Some versions of the PP require action to prevent (uncertain) risk, or require the proponent of an activity to prove safety before the activity may go forward.
  - But: precaution can itself yield new risks (R-R) via foregone benefits of restricted technology; risk of substitutes; etc.
  - So: the PP can block itself.

- Solution: Confront multi-risk world. Incorporate multi-risk approach into "optimal precaution."
  - In reality, precaution is often moderated by R-R.

- Emergence of risks with uncertainty, irreversibility, catastrophe: can arise on all sides.
  - Uncertainty analysis must be multi-risk
  - If precaution is warranted, then ancillary risks also warrant precaution.
  - Type and degree of uncertainty may vary across risks.

Public perception of risk is multifaceted

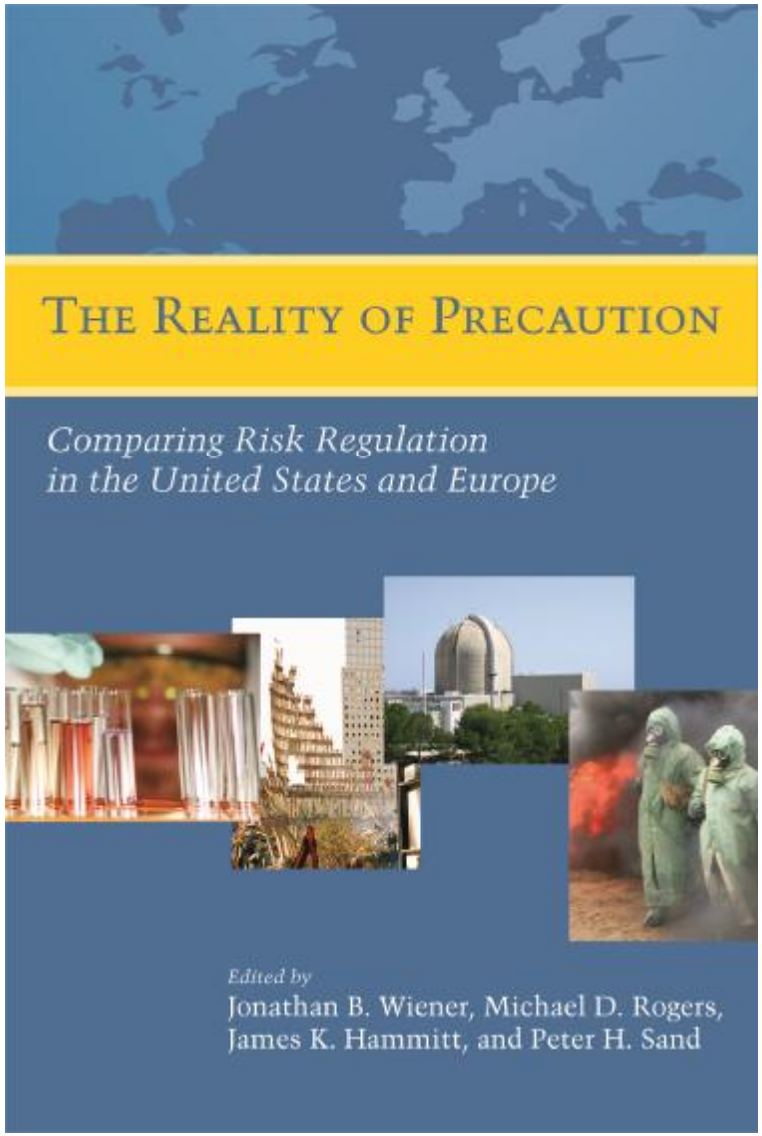
- Not just p(I) …
- Unfamiliarity
- Dread
- Availability
- Identified victim
- Identified villain
- Perceived benefits
- Cultural risk selection
- Etc.

Precaution: Comparative

Are some societies more precautionary, or more concerned about risk-risk tradeoffs, than others?

USA vs. EU ?

A ten-year, multi-risk, multi-author research project.



(RFF Press / Earthscan / Routledge, 2011)

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

Reversal over time relative precaution in the US vs. EU ?

"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" or "flip-flop" in relative US/EU precaution between 1970-90 and 1990-2010. Why: shifts in public opinion, leadership, IA using BCA.

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

Comparative Precaution: Parity and Particularity

EU

1970s – 80s:

- Marine environment
- Guns

1990s - present:

- Hormones in Beef, rBST
- GM foods / crops
- Climate
- Toxic Chemicals

US

1970s – 80s:

- New drug approval
- Strat. Ozone (CFCs)
- Nuclear power
- Endangered species
- Lead (Pb) in gas/petrol

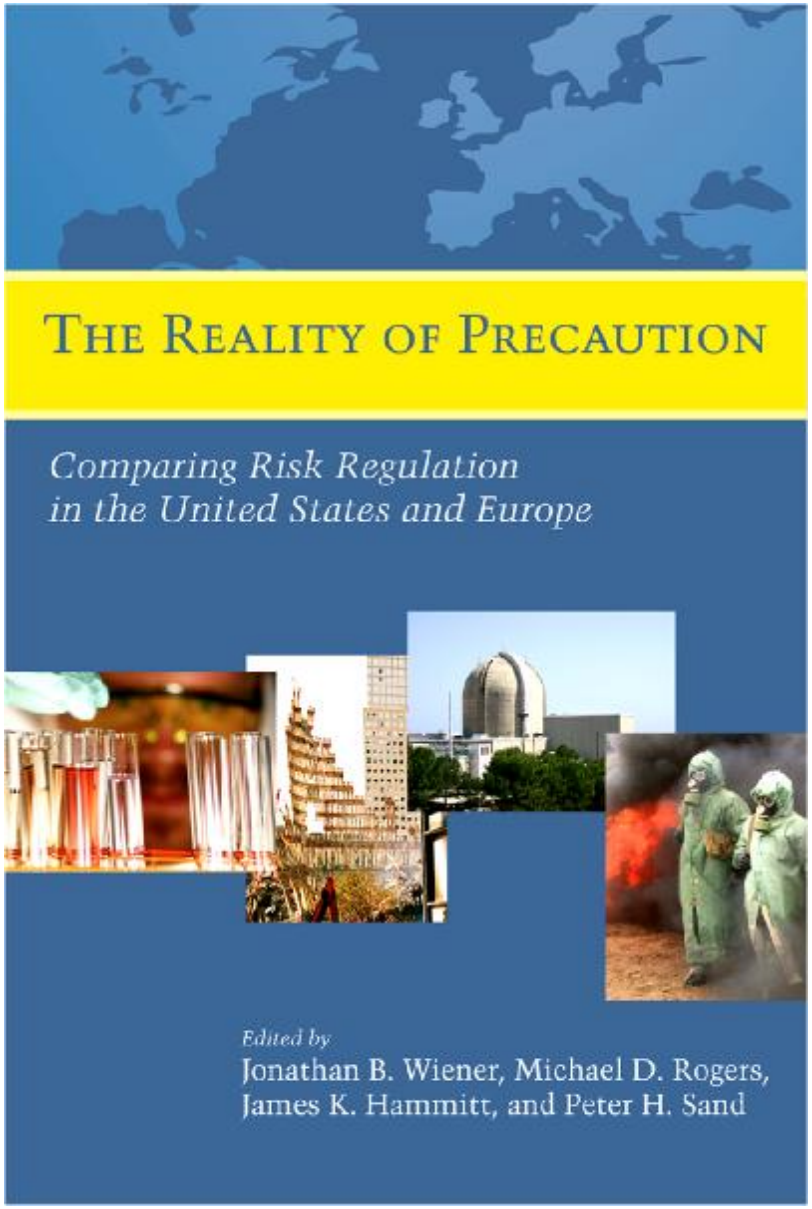
1990s - present:

- BSE/vCJD in Beef, Blood
- Smoking tobacco
- Particulate Matter (PM) air pollution (esp. diesel)
- Terrorism

Are some societies "more precautionary" than others?

We studied US and Europe, 1970-2010:

- A dozen case studies.
- Quantitative comparison of a random sample of 100 from a universe of 2878 risks.
- Explanatory factors.
- Impacts.



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Key findings:

- *Selective* application of precaution, in both Europe and the USA.
- No strong US-EU trend: < 6% shift.
- Why: Not 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.

What are the actual effects of risk regulation? Can we learn?

- From Impact Assessments – ex ante, and ex post
  - Retrospective RIA: EO 13563 (Jan. 2011)
  - Need "full portfolio impact assessment" to study multiple-risk impacts (R-R)
- From observed variation in actual regulatory policies
  - Across risks, across jurisdictions, across policy designs
  - Wiener 1998: need "outcomes studies" of risk regulation
  - Wiener & Alemanno 2014: trade agreements (e.g. TTIP) should not fixate on policy harmonization/convergence, but should foster study of policy variation
- From purposeful policy experimentation
  - Greenstone, Ludwig, Listokin, et al.
- From crisis events (new Duke project, "Recalibrating Risk")
  - Which type of policy change (if any) is spurred by which type of crisis?
  - Mega-catastrophes may not spur policy change: neglected ex ante, but too damaging ex post; best case for precaution
- Toward a global policy laboratory

What can we learn about risk regulation from synthetic biology?

- An emerging new technology with wide application
- Ability of products to reproduce and propagate once released …
- Risk perceptions and framing
- Risk-reducing applications from syn bio?
- Risk assessment applications from syn bio? E.g. re new toxicity testing on tissue clusters; microbiome variability; etc.
- Policy design
  - Regulation to ensure safety without stifling innovation or incurring adverse side effects (risk-risk tradeoffs).
  - Role of safety norms among syn bio community – especially if it is difficult for public regulators to monitor many small practitioners.
- Learning from policy variation – observed, experimental. US-EU policies and relations? Other countries?

Thank you.

www.law.duke.edu/fac/wiener