SYLLABUS

WWS 586e

Risk Policy and Regulation

Spring 2006
Wednesdays, 1-4 pm
(Location TBA)

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Overview:

Federal and state government, and the U.S. public, are increasingly turning to quantitative risk assessment (QRA) and cost-benefit analysis (CBA) to help set standards and make research decisions affecting health, safety, and environmental protection. This course prepares students to critically evaluate risk and cost-benefit analyses against cutting-edge information about their validity, in order to help make environmental decisions that are responsive to science, economics, and public values.

Course Requirements:

1. Two problem sets (one on decision-making under uncertainty, one on risk assessment techniques and interpretation): 20% each

2. One short (approx. 1500-word) essay: 10%

3. Oral presentation (pairs of students arguing pro/con a particular regulatory proposal): 10%

4. Final paper (approx. 20 pages)—analyzing a particular "risk-risk tradeoff" in light of new information about the primary and offsetting risk: 30%

5. Class Participation: 10%

Outline of Lecture/Discussion Topics:

Week 1 (February 8)

Introduction: *How science, economics, policy, and politics influence choices in protecting health, safety, and the environment.*

Topics:

- Regulation as, depending on point of view, improper coercion or "those wise restraints that make us free"
- Spectrum of uses for quantitative risk assessment (QRA) and cost-benefit analysis (CBA)
- Historical growth of QRA/CBA; watershed events
- Fundamental distinction between individual probability of harm and population consequences
- Tension between technocratic and participatory styles of decision-making
- Difficulties in interpreting quantitative information ("innumeracy")
- Conceptual/bureaucratic separation of "facts" versus "values"—is it possible/is it desirable?

Required Readings:

- ❖ William D. Ruckelshaus (1985), "Risk, Science, and Democracy," *Issues in Science and Technology*, **1,** pp. 19-38.
- ❖ Excerpts (pp. 1-22, 43-53) from Philip K. Howard, **The Death of Common Sense: How Law is Suffocating America**, 1994 (Random House).
- ❖ Excerpts (pp. 3-29) from Stephen Breyer, **Breaking the Vicious Circle: Toward Effective Risk Regulation**, 1993 (Harvard Univ. Press).
- ❖ Adam M. Finkel, book review of **Risk and Reason** (Cass R. Sunstein, 2002), *Journal of Industrial Ecology*, **9(4)**, pp. 243-247.
- ❖ Nicholas A. Ashford (1988), "Science and Values in the Regulatory Process," *Statistical Science,* **3(3)**, pp. 377-383.
- ❖ William Crain (1995), "Risks and Public Policy: An Interview with John D. Graham," *IEEE Power Engineering Review*, December, pp. 3-4.

- Clyde Wayne Crews, Jr. (2005), "Ten Thousand Commandments: An Annual Snapshot of the Federal Regulatory State," Cato Institute, Washington, DC.

Week 2 (Feb. 15)

Decision Theory I: *The art and skill of deciding when to decide and what to do.*

Topics:

- Distinction between good outcome and good decision
- Basic probability theory (frequentist and Bayesian perspectives)
- Basic statistical decision theory ("decision trees," sensitivity analysis)
- How to weigh outcomes (progression from expected-value thinking to expected-utility to prospect theory/regret/etc.)

Required Readings:

- Robert E. Rubin, "A Healthy Respect for Uncertainty," commencement address at the University of Pennsylvania, May 17, 1999.
- "Decisions, Decisions," *Discover*, June 1985.
- Geoffrey Churchill and Thomas Whalen, "Decisions under Uncertainty" (unpublished ms.)

Week 3 (Feb. 22)

Decision Theory II: *Pitfalls and traps in decision-making.*

Topics:

- Calculating the value of new information
- Risk perception and communication

Required Readings:

- John S. Evans, Neil C. Hawkins, and John D. Graham (1988), "The Value of Monitoring for Radon in the Home: A Decision Analysis," *JAPCA*, **38,** pp. 1380-1385.
- Paul Slovic (1987). "Perception of Risk," *Science*, **236,** pp. 280-5.
- Peter M. Sandman (2004). "When People are "Overreacting' to Risk," *The Synergist*, February, pp. 23-4.
- Kathryn E. Kelly (1991). "The Myth of 10-6 as a Definition of 'Acceptable Risk'," presentation the 84th Annual Meeting of the Air and Waste Management Association, June 16.

Week 4 (March 1)

<u>The Regulatory Process:</u> *How agencies set their agendas, conduct analyses, interact with stakeholders, and defend their work from challenge.*

<u>Topics:</u>

- Process map of regulation: "access points" where analysis is required (from agenda-setting, through proposed and final rules, through judicial and Congressional challenge to agency action, to retrospective evaluation of program effectiveness)
- Court decisions requiring, forbidding, and allowing discretionary analysis; extent to which courts have deferred to agency's conduct of those analyses that are mandatory

<u>Required Readings:</u>

- ICF Inc. "The Reg Map: Informal Rulemaking" (poster)
- Cass R. Sunstein (2002), "Of Courts and Law: Cost-Benefit Default Principles." Chapter 8 (pp. 191-228) in **Risk and Reason**, Cambridge University Press, 2002.
- Stuart Shapiro (2005), "Two months in the Life of the Regulatory State," *Administrative and Regulatory Law News*, **30(3),** pp. 12-15.
- Office of Management and Budget (2005) "Making Government More Effective," from The U.S. Budget for Fiscal Year 2006, pp. 49-58.

Week 5 (March 8)

<u>Survey of QRA I:</u> *Raw materials for conducting risk assessments; model choice; introduction to exposure assessment and dose-response analysis*

Topics:

- Data sources
- Keeping track of units
- Stability versus feedback in model structure
- 4-step paradigm for QRA process

Required Readings:

- ❖ Excerpts (pages 1-14, 29-41, 53-84, and 139-152) from Lorenz Rhomberg (1996). "A Survey of Methods for Chemical Health Risk Assessment among Federal Regulatory Agencies" (report for the Presidential/Congressional Commission on Risk Assessment and Management).
- ❖ Tom McKone and P. Barry Ryan (1989). "Human Exposure to Chemicals through Food Chains," *Environmental Science and Technology,* **23,** pp. 1154-63.
- ❖ Martha Crawford and Richard Wilson (1996). "Low-Dose Linearity: The Rule or the Exception?" *Human and Ecological Risk Assessment,* **2,** pp. 305-330.

Week 6 (March 15)

Survey of QRA II: *"Default" models and departures therefrom; introduction to uncertainty.*

Topics:

- Evidentiary standards for supplanting "default" models
- Case studies of agencies abandoning defaults
- Types of uncertainty
- Investment example of multiple characterizations of uncertainty

Required Readings:

- ❖ National Academy of Sciences (Committee on Risk Assessment of Hazardous Air Pollutants, 1994), **Science and Judgment in Risk Assessment,** pp. 79-84, Appendices N-1, N-2.
- ❖ Franklin E. Mirer (2003), "Distortions of the "Mis-Read' Book: Adding Procedural Botox to Paralysis by Analysis," *Human and Ecological Risk Assessment,* **9(5),** pp. 1129-1143.
- ❖ Excerpts from Mark E. Shere (1995). "The Myth of Meaningful Environmental Risk Assessment," *Harvard Environmental Law Review,* **19,** pp. 409-492.

- ❖ "Fundamental Concepts in Risk Assessment: Dealing with Uncertainty" (2000). Network for Environmental Risk Assessment and Management, University of Waterloo, Ontario, Canada.
- ❖ Adam M. Finkel (1995). "Towards Less Misleading Comparisons of Uncertain Risks: The Example of Aflatoxin and Alar." *Environmental Health Perspectives,* **103(4),** 376-385.
- ❖ Short excerpt (pp. 88-91) from Final Report of the Presidential/Congressional Commission on Risk Assessment and Management, 1997.
- ❖ "Life is Lognormal," Webpage developed by Eckhard Limpert and Werner Stahel (Swiss Federal Institute of Technology, Zurich): http://www.inf.ethz.ch/personal/gut/lognormal/brochure.html

Week 7 (March 29)

Survey of QRA III: *Interindividual variability in risk.*

Topics:

- Variation in exposure
- Biological basis of variation in susceptibility
- Concerns over individual genetic information
- Variation in preferences
- Medical decision-making

Required Readings:

- ❖ Dale Hattis (2004). "The Conception of Variability in Risk Analysis: Developments since 1980." Chapter 2(pp. 15-45) in **Risk Analysis and Society: An Interdisciplinary Characterization of the Field,** Timothy McDaniels and Mitchell J. Small, eds., Cambridge University Press.
- ❖ Stephen Jay Gould: "The Median Isn't the Message," *Discover,* June 1985
- ❖ Excerpts (Chapters 1, 7, 12, 14, and 20) from Stephen Schneider (2005), **The Patient from Hell.**
- ❖ Excerpts (pp. 297-300 and 313-326) from Adam M. Finkel (1995) "A Quantitative Estimate of the Variations in Human Susceptibility to Cancer and Its Implications for Risk Management." Chapter in S. Olin, et al., eds., **Low-Dose Extrapolation of Cancer Risks: Issues and Perspectives,** International Life Sciences Institute.

Week 8 (April 5)

<u>Regulatory Economics:</u> *How economists convert risks into dollar terms, and compare them to the costs of proposed risk-reducing interventions.*

<u>Topics:</u>

- Valuation of mortality, morbidity, and ecological harm
- Discounting of future consequences
- Estimation of regulatory costs
- Forecasting of compliance
- Retrospective program evaluation

<u>Required Readings:</u>

- ❖ Michael Harris (1996), "For the Student: Environmental Economics," *Australian Economic Review*, 4th Quarter 1996, pp. 449-465.
- ❖ Eban Goodstein and Hart Hodges (1997), "Polluted Data: Overestimating Environmental Costs," *The American Prospect*, **35,** Nov./Dec., pp. 64-69.
- ❖ John D. Graham (2003). "Valuing Health: an OMB Perspective," speech given at Resources for the Future, Washington, D.C., Feb. 13.
- ❖ Excerpts (Executive Summary, Chapter 3, and Chapter 6) from Lisa Robinson (2004), "Current Federal Agency Practices for Valuing the Impacts of Regulations on Human Health and Safety," report to the IOM Committee to Evaluate Measures of Health Benefits for Environmental, Health, and Safety Regulation.
- ❖ Excerpts from *Gauging Control Technology and Regulatory Impacts in Occupational Safety and Health: An Appraisal of OSHA's Analytic Approach,* Office of Technology Assessment, OTA-ENV-635, Sept. 1995.

Week 9 (April 12)

<u>Scientific Integrity:</u> *Issues of expertise, bias, the interplay of science and values, and the potential role for peer review and other process improvements.*

<u>Topics:</u>

- Politicization of science
- Disclosure, recusal, and peer review policies, both in scientific publication and in the regulatory context

<u>Required Readings:</u>

- ❖ Letter from Rep. Henry Waxman to Rep. Joe Barton, July 1, 2005.

- ❖ Excerpts from U.S. Government Accountability Office (2005), *Decision Process to Deny Initial Application for Over-the-Counter Marketing of the Emergency Contraceptive Drug 'Plan B' was Unusual,"* GAO-06-109.
- ❖ Paul Singer (2005), "By the Horns," *National Journal*, March 26, pp. 898-904.
- ❖ David Michaels (2005), "Doubt is Their Product," *Scientific American,* June 2005, pp. 96-101.
- ❖ Roger Pielke, ed. (2004), *Report on the Misuse of Science in the Administrations of George H.W. Bush (1989-1993) and William J. Clinton (1993-2001),* University of Colorado, June 2004.
- ❖ Excerpts from *EPA's Science Advisory Board Panels: Improved Policies and Procedures Needed to Ensure Independence and Balance,* U.S. General Accounting Office, GAO-01-536.
- ❖ Jeff Ruch (2005), "Improving Information Quality in the Federal Government," testimony before the House Committee on Government Reform, Subcommittee on Regulatory Affairs, July 20, 2005.

Week 10 (April 19)

<u>Regulatory "Reform" in Congress, OMB, and elsewhere:</u> *Recent attempts to change the way agencies assess and manage risks.*

<u>Topics:</u>

- Legislative proposals in the 1990s
- OMB guidance documents
- The Data Quality Act
- Emphasis on the idea of "risk-risk tradeoffs"
- "Macro" ideas for reform: the "regulatory budget," regulatory triage, etc.

<u>Required Readings:</u>

- ❖ Thomas O. McGarity, Sidney Shapiro, and David Bollier (2005). **Sophisticated Sabotage: The Intellectual Games used to Subvert Responsible Regulation,** introduction, 15 pp.
- ❖ Charles N. Herrick (2004), "Objectivity versus Narrative Coherence: Science, Environmental Policy, and the U.S. Data Quality Act," *Environmental Science and Policy***, 7**, pp. 419-433.
- ❖ Jonathan B. Weiner (1998), "Managing the Iatrogenic Risks of Risk Management," *RISK: Health, Safety & Environment*, **9,** pp. 39-82.

- Cass R. Sunstein (1996), "Health-Health Tradeoffs," *Chicago Working Papers in Law and Economics*, No. 42, 36 pp.
- Miscellaneous materials from Congressional "regulatory reform" proposals and commentary (A. Finkel personal files).
- James S. Kunen (1995), "Rats: What's for Dinner? Don't Ask," *The New Yorker*, March 6, 1995, pp. 7-8.
- Bob Davis (1992), "What Price Safety? Risk Analysis Measures Need for Regulation, but it's No Science," *Wall Street Journal*, Aug. 6, 1992, pg. A1.
- Office of Management and Budget (2006), *Proposed Risk Assessment Bulletin*, January, 26 pp.

Week 11 (April 26)

Emerging Alternatives to Traditional Rulemaking **and** The Political Landscape of Cost-Benefit Analysis: (1) New ideas to control hazards in more efficient and more participatory ways; and (2) Prospects for the future in light of the polarizing effect of CBA.

Topics:

- Tradeable permits
- Information dissemination
- EPA's "Project XL"
- OSHA's "enforceable partnerships"
- Using settlement negotiations to move "beyond compliance"
- Corporate social responsibility and social investment
- "Management-based regulation"
- Antipathy of many NGOs to risk and cost-benefit analysis
- The "precautionary principle" as a possible alternative
- Hybrid alternatives, including technology options analysis and embedding precaution within QRA/CBA

Required Readings:

- Cary Coglianese and David Lazer (2003), "Management-Based Regulation: Prescribing Private Management to Achieve Public Goals," *Law and Society Review*, **37**, pp. 691-730.

- ❖ Excerpts (Chapters 2 and 9) from Frank Ackerman and Lisa Heinzerling (2004), **Priceless: On Knowing the Price of Everything and the Value of Nothing,** The New Press, New York.
- ❖ Ellen K. Silbergeld (1993), "Risk Assessment: The Perspective and Experience of U.S. Environmentalists," *Environmental Health Perspectives,* **101,** pp. 100-104.
- ❖ Alon Tal (1997), "A Failure to Engage," *The Environmental Forum*, Jan/Feb., pp. 13-21.

Week 12 (May 3)

Student Presentations

Topics:

Regulatory case studies will be determined based on student interest. Possible examples include:

- 2006 proposal to reduce fine particulate matter (EPA)
- Mercury reductions from power plant emissions (EPA)
- "Plan B" as over-the-counter drug (FDA)
- Tire underinflation sensors (DOT)
- Snowmobile use in Yellowstone (DOI)
- Ergonomic hazards (OSHA)
- 2006 final rule to reduce chromium exposure (OSHA)