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Randall Lutter has more than 25 years of senior experience in the management and evaluation of programs to protect health, safety and the environment. From 2003 to 2009, Lutter served at the Food and Drug Administration in different capacities, including as Chief Economist and Deputy Commissioner for Policy. He played a leadership role developing new policies affecting regulation of genetically engineered animals, animal clones, prevention of mad cow disease, user fee programs for new drugs and devices, communicating risks from unapproved imported drugs, and the management of FDA's advisory committees and strategic planning. Lutter also served at the Office of Management and Budget in the Office of Information and Regulatory Affairs from 1991 to 1997 and in 2009-2010, and from 1997 to 1998 he was senior economist for regulation and the environment at the President's Council of Economic Advisers.

Lutter was resident scholar with the American Enterprise Institute and fellow with the AEI-Brookings Joint Center for Regulatory Studies, where he wrote about a variety of regulatory approaches to address health, safety and environmental risks, covering topics from air pollution and greenhouse gases, to toxic substances, food safety and genetically engineered animals. He taught at the State University of New York at Buffalo after earning a Ph.D. in economics at Cornell University. With Jason F. Shogren, he co-edited *Painting the White House Green: Rationalizing Environmental Policy Inside the Executive Office of the President*, 2004, RFF Press. He has testified before Congressional committees. His work has appeared in the *American Economic Review*, *Environmental Science & Technology*, the *Journal of Political Economy*, *Risk Analysis*, *Science* and the *Administrative Law Review* as well as publications like *Politico* and *Regulation*.

Academic Research

Manuscripts / Works in Progress

Arindam Nandi, Randall Lutter and Ramanan Laxminarayan, "The Association between Breastfeeding and Future Schooling Outcomes and Educational Performance: Longitudinal Evidence from India" July 2016. An earlier version was presented at the Annual Meetings of the Society for Risk Analysis, Washington D.C., 2015.

Peer-Reviewed Articles

1. Arthur G. Fraas and Randall Lutter, 2016, "How Effective Are Federally Mandated Information Disclosures?" *Journal of Benefit-Cost Analysis* / Volume 7 / Issue 02 / Summer 2016, pp 326-349. An earlier version of this paper was presented at the annual meetings of the Society for Risk Analysis, December 2013, the Society for Benefit-Cost Analysis, March 2014, and at a conference "Does Disclosure Have a Future?" at the University of Virginia Law School.

2. Randall Lutter, Linda Abbott, Rick Becker, Chris Borgert, Ann Bradley, Gail Charnley, Susan Dudley, Alan Felsot, Nancy Golden, George Gray, Daland Juberg, Mary Mitchell, Nancy Rachman, Lorenz Rhomberg, Keith Solomon, Stephen Sundlof, and Kate Willett, 2015, "Improving Weight of Evidence Approaches to Chemical Evaluations", *Risk Analysis* Article first published online: 16 DEC 2014 DOI: 10.1111/risa.12277. <http://onlinelibrary.wiley.com/doi/10.1111/risa.12277/full>
3. Randall Lutter, 2014, "A Bounding Analysis of the Benefits of Reducing Perchlorate Concentrations in Drinking Water", *Risk Analysis*, Oct 5; 34(10):1944-56. Epub 2014 Sep 5.
4. Randall Lutter, 2013, "The Role of Retrospective Analysis and Review in Regulatory Policy," *Journal of Benefit-Cost Analysis*. 4(1):17-38. Senators Ron Johnson and Mark Warner cited an earlier version of this paper in a July 3, 2012 letter requesting that the General Accountability Office report on federal agencies' retrospective regulatory reviews.
5. Randall Lutter, Craig Barrow, Christopher J. Borgert, James W. Conrad Jr., Debra Edwards, Allan Felsot, 2013, "Data Disclosure for Chemical Evaluations", *Environmental Health Perspectives* 121:145–148. <http://dx.doi.org/10.1289/ehp.1204942> Lutter et al. also replied to a letter to the editor of *EHP* regarding this article, at <http://ehp.niehs.nih.gov/1206438r/> .
6. Chessa Lutter and Randall Lutter, "Fetal and Early Childhood Undernutrition, Mortality and Lifelong Health", *Science*, 337:1495-99. September 21, 2012. <http://www.sciencemag.org/content/337/6101/1495>
7. Art Fraas and Randall Lutter, "Uncertain Benefits Estimates for Reductions in Fine Particle Concentrations", *Risk Analysis, An International Journal*, August 2012. DOI: 10.1111/j.1539-6924.2012.01883.x <http://onlinelibrary.wiley.com/doi/10.1111/j.1539-6924.2012.01883.x/abstract> . Cited in Forbes, July 29th, 2013. Also, Fraas and Lutter, 'Reply to Letter by Fann, Lamson, Anenberg, and Hubbell, Regarding Fraas & Lutter Article: "Uncertain Benefits Estimates for Reductions in Fine Particle Concentrations"', *Risk Analysis, An International Journal* 2013, doi: 10.1111/risa.12043
8. Art Fraas and Randall Lutter, 2012, "Efficient Pollution Regulation: Getting the Prices Right: Comment," *American Economic Review*, 102(1): 602–07, 2012. DOI:10.1257/aer.102.1.602, <http://www.aeaweb.org/articles.php?doi=10.1257/aer.102.1.602> An earlier version appeared as RFF Discussion Paper 11-36.
9. Art Fraas and Randall Lutter, "The Challenges of Improving the Economic Analysis of Pending Regulations: The Experience of OMB Circular A-4", *Annual Review of Resource Economics*, 3:71-85, 2011, DOI: 10.1146/annurev-resource-083110-120042,

<http://www.annualreviews.org/doi/abs/10.1146/annurev-resource-083110-120042> An earlier version of this paper appeared as RFF Discussion Paper 10-54.

10. Vernon, John A., Joseph Golec, Randall Lutter, and Clark Nardinelli, “An Exploratory Study of FDA New Drug Review Times, Prescription Drug User Fee Acts, and R&D Spending”, *The Quarterly Review of Economics and Finance*, Vol. 49, Issue 4, Pages 1260-1274, November 2009. An earlier version of this paper appeared as AEI-Brookings Joint Center for Regulatory Studies, Working Paper 6-21, September 2006.
11. McWilliam, Andrew, Randall Lutter and Clark Nardinelli, “Healthcare Impact of Personalized Medicine Using Genetic Testing: An Exploratory Analysis for Warfarin”, *Personalized Medicine*, 5(3), 279-284, 2008. An earlier version appeared as AEI-Brookings Joint Center for Regulatory Studies, Working Paper 6-23, November 2006.
12. Randall Lutter and Tucker, Katherine, “Unacknowledged Health Benefits of Genetically Modified Food: Salmon and Heart Disease Deaths,” *AgBioForum*, 5(2), 59-64, 2003, <http://www.agbioforum.org/v5n2/v5n2a04-lutter.htm>
13. Randall Lutter and Elisabeth Irwin, “Mercury in the Environment: A Volatile Problem”, *Environment: Science and Policy for Sustainable Development*, Vol. 44, Number 9, 24-40, November 2002.
14. Randall Lutter and Jason F. Shogren, “Tradable Permit Tariffs: How Local Air Pollution Affects Carbon Emissions Permit Trading”, *Land Economics*, Vol. 78, No. 2, 159-170, May 2002.
15. Randall Lutter and Elizabeth Mader, “Lead in Soil: Is Your Backyard Safer Than A Hazardous Waste Site?” *EM Magazine*, Air and Waste Management Association, 16-21, September 2001. An earlier version of this paper appeared as AEI-Brookings Joint Center for Regulatory Studies, Working Paper 00-03, June 2000.
16. Randall Lutter, “Getting the Lead Out Cheaply: Comments on EPA’s Proposed Hazard Standards”, *Environmental Science & Policy*, Vol. 4, 13-21, 2001. An earlier version of this paper appeared as AEI-Brookings Joint Center for Regulatory Studies, Working Paper 99-5, May 1999.
17. Randall Lutter, “Developing Countries’ Greenhouse Emissions: Uncertainty and Implications for Participation in the Kyoto Agreement”, *Energy Journal*, Vol. 21, No. 4. 93- 120, October 2000.
18. Randall Lutter, “Food Irradiation: The Forgotten Solution to Food-Borne Illness”, *Science*, Vol. 286, 2275-2276, December 17, 1999.
19. Randall Lutter, John F. Morrall III, and W. Kip Viscusi, “The Cost-Per-Life-Saved

Cutoff for Safety-Enhancing Regulations”, *Economic Inquiry*, Vol. 37, No. 4., 599-608, October 1999.

20. Randall Lutter and Christopher Wolz, “UV-B Screening by Tropospheric Ozone: Implications for the National Ambient Air Quality Standard”, *Environmental Science & Technology*, Vol. 31, 142a-146a, 1997.
21. Arthur Fraas and Randall Lutter, “Abandonment of Residential Housing and the Abatement of Lead-based Paint Hazards”, *Journal of Policy Analysis and Management*, Vol. 15, 424-429, 1996.
22. Randall Lutter and John F. Morrall, III, “Health-Health Analysis: A New Way To Evaluate Health and Safety Regulations”, *Journal of Risk and Uncertainty*, Vol. 8, 43-66, 1994.
23. Isaac Ehrlich, Georges Gallais-Hamonno, Zhiqiang Liu, and Randall Lutter, “Productivity Growth and Firm Ownership: An Analytical and Empirical Investigation,” *Journal of Political Economy*, Vol. 102, No. 5 1006–1038, October 1994.
24. John Logan and Randall Lutter, “Guaranteed Lowest Prices: Do They Facilitate Collusion?” *Economics Letters*, Vol. 31, 189-192, 1989.

Law Articles and Briefs

25. Arthur Fraas and Randall Lutter, “On the Economic Analysis of Regulations at Independent Regulatory Commissions: Would Greater Use of Economic Analysis Improve Regulatory Policy at Independent Regulatory Commissions?” “63 *Administrative Law Review*, (Special Edition) 213, (2011). An earlier version appeared as RFF Discussion Paper 11-16 and was presented at RFF’s 2011 conference “Can Greater Use of Economic Analysis Improve Regulatory Policy at Independent Regulatory Agencies?”
26. Randall Lutter and Dallas Burtraw, “On the Gains from Integrating Markets for Permits to Emit Related Pollutants”, *Fordham Environmental Law Journal*, Fall 2002. Also at <http://aei.brookings.org/admin/pdffiles/phpP4.pdf>. Presented at EPA NCEE Symposium on Cost-Effective Analysis for Multiple Benefits, September 2003.
27. Randall Lutter and Howard Gruenspect, “Assessing Benefits of Ground Level Ozone: What Role for Science in Setting National Ambient Air Quality Standards?” *Tulane Environmental Law Journal*, Vol. 15, Issue 1, 85-96, Winter 2001.
28. Randall Lutter, “Sovereignty, Federalism, and the Identification of Local Environmental Problems,” *Chicago Journal of International Law*, Vol. 2, No. 2. 447-457, Fall 2001.
29. Brief Amici Curiae of AEI-Brookings Joint Center for Regulatory Studies, to the

Supreme Court of the United States, *American Trucking Associations, Inc., et al., v. Carol M. Browner, Administrator of the Supreme Court et al.* AEI-Brookings Joint Center for Regulatory Studies, July 21, 2000.

Book Chapters

30. Randall Lutter, “Head in the Clouds Decision-Making: EPA’s Air Quality Standards for Ozone”, Chapter Two in Randall Lutter and Jason F. Shogren, editors, *Painting the White House Green: Rationalizing Environmental Policy Inside the Executive Office of the President*, 2004, RFF Press.
31. Randall Lutter and Elizabeth Mader, “Litigating Lead-Based Paint Hazards: Is It A Solution?” in *Regulation through Litigation*, Kip Viscusi, ed., AEI-Brookings Joint Center for Regulatory Studies, 2002.

Professional Papers and Reports

32. Susan Dudley, Richard Belzer, Glenn Blomquist, Timothy Brennan, Christopher Carrigan, Joseph Cordes, Louis A. Cox, Arthur Fraas, John Graham, George Gray, James Hammitt, Kerry Krutilla, Peter Linquiti, Randall Lutter, Brian Mannix, Stuart Shapiro, Anne Smith, W. Kip Viscusi & Richard Zerbe, “Consumer’s Guide to Regulatory Impact Analysis: Ten Tips for Being an Informed Policymaker”, The George Washington University Regulatory Studies Center, Washington D.C. February 2017, <https://regulatorystudies.columbian.gwu.edu/consumer%E2%80%99s-guide-regulatory-impact-analysis>
33. Randall Lutter and David Zorn, “On the Benefits and Costs of Public Access to Data Used to Support Federal Rulemaking”, Mercatus Center, George Mason University, September 2016. <http://mercatus.org/publication/benefits-and-costs-public-access-data-used-support-federal-policy-making> A related opinion piece is at <https://smartregs.org/the-data-that-our-government-uses-must-be-transparent-caa16b3dc19d#.18y5dbpr5>
34. Dajun Lin, Randall Lutter and Christopher J. Ruhm, “Cognitive Performance and Labor Market Outcomes”. NBER Working Paper No. 22470, July 2016. <http://www.nber.org/papers/w22470>. Presented at the World Bank, July 2016, and at the Annual Meetings of the Society for Risk Analysis, Washington D.C., 2015.
35. Abigail Colson, Roger Cooke and Randall Lutter, “How Does Breastfeeding Affect IQ? Applying the Classic Model of Structured Expert Judgment”, Resources for the Future Discussion Paper 16-28 July 2016
36. Marc Hafstead and Randall Lutter, “What Is the Economic Value of Improved Labor Market Outcomes from Infant Nutrition? The Case of Breastfeeding in the United

States”. Resources for the Future Discussion Paper 16-29, July 2016. An earlier version was presented at the annual meetings of the Society for Risk Analysis, Washington D.C., 2015.

37. Randall Lutter and David Zorn, “Improving Regulatory Cooperation Between the FDA and the EU”, Report for the George Washington University Regulatory Studies Center, April 2016. Published as part of a five paper series on US-EU Regulatory Cooperation: Lessons and Opportunities. <https://regulatorystudies.columbian.gwu.edu/us-eu-regulatory-cooperation-lessons-and-opportunities> . Referenced by Susan Dudley, “Transatlantic Regulatory Cooperation Needs Both Cooperation and Competition”, Forbes, April 26, 2016. Presented at a conference on International Regulatory Cooperation in Practice, at the EU Delegation to the U.S., September 15th, 2016.
38. Art Fraas, Randall Lutter, Zachary Porter and Alexander Wallace, “The Energy Paradox and the Adoption of Energy Saving Technologies in the Trucking Industry”, March, 2016, Working Paper, Mercatus Center, George Mason University. <http://mercatus.org/publication/energy-paradox-and-adoption-energy-saving-technologies-trucking-industry>. See also <http://www.rff.org/blog/2016/testing-energy-paradoxes-competitive-industries>. We presented this paper at the annual meetings of the Society of Benefit-Cost Analysis in March, 2016, and submitted it to the EPA and NHTSA as a public comment on a proposed rule regulating heavy-duty truck trailers.
39. Art Fraas, Randall Lutter, Susan Dudley, Ted Gayer, John Graham, Jason F. Shogren, W. Kip Viscusi, Letter: “Social cost of carbon: Domestic duty”, *Science*, 05 Feb 2016: Vol. 351, Issue 6273, pp. 569 DOI: 10.1126/science.351.6273.569-b <http://science.sciencemag.org/content/351/6273/569.2> . This letter was posted or cited at the Brookings Institution, <https://www.brookings.edu/opinions/how-much-will-climate-change-rules-benefit-americans/>, as well as the George Washington University Regulatory Studies Center, Resources for the Future and the University of Wyoming. A closely related letter to the National Academy of Sciences is available at <http://www.rff.org/blog/2016/should-federal-regulatory-agencies-report-benefits-americans-mandated-reductions>
40. Randall Lutter and David Zorn, “Reinforcing Reproducibility: What Role for the Federal Government?” *Regulation*, Winter 2015-16. 15-16, http://object.cato.org/sites/cato.org/files/serials/files/regulation/2015/12/regulation-v38n4-8_4.pdf#page=10
41. Randall Lutter, “Herding Genetically Engineered Animals to Market”, Resources for the Future Blogpost, December 16th, 2015, <http://www.rff.org/blog/2015/herding-genetically-engineered-animals-market>. Also posted at the George Washington University Regulatory Studies Center: <http://regulatorystudies.columbian.gwu.edu/herding-genetically-engineered-animals-market>

42. Randall Lutter, “How Effective Are Federal Food Safety Regulations? The Case of Eggs and *Salmonella* Enteritidis”, RFF Discussion Paper 15-24 | June 2015, <http://www.rff.org/Publications/Pages/PublicationDetails.aspx?PublicationID=22570>, Presented at RFF, December 2014 and the Society for Benefit-Cost Analysis, March 2015. Featured in <http://www.rff.org/events/event/2015-10/real-outcomes-federal-environmental-regulations-lessons-performance-data>
43. Art Fraas and Randall Lutter, “How Much Would EPA’s Greenhouse Gas Rule Cool the Earth?” *Regulation*, Winter 2014-15, 4-5. <http://object.cato.org/sites/cato.org/files/serials/files/regulation/2014/12/regulation-v37n4-9.pdf>
44. Joe Aldy, Art Fraas and Randall Lutter, “OMB: Obscurity in Management and Budget”, *Regulation*, Winter 2013-14, 5-6, [OMB: Obscurity in Management and Budget?](#)
45. Randall Lutter, Letter: “Waiving Concerns About Conflicts of Interest”, *Science*, September 13th, 2013, 341:1173.
46. Art Fraas and Randall Lutter, “Review of *Using Marginal Damages in Air Pollution Policy: a Study of Air Pollution in the United States*, by Muller and Mendelsohn”, *Journal of Economic Literature*, June 2013.
47. Nathan Richardson and Randall Lutter, “Making Sense of Ozone”, RFF Policy Commentary, September 19, 2011.
48. Art Fraas and Randall Lutter, “Do Some NO_x Emissions Have Negative Environmental Damages? Evidence and Implications for Policy”, *Environmental Science & Technology*, September 2011, Vol. 45, No.17, <http://pubs.acs.org/doi/abs/10.1021/es202622z>
49. Randall Lutter, “Food-Borne Illness Outbreak: Data Disclosure, Performance, and Recommendations for Reform”, *Regulation Outlook*, American Enterprise Institute for Public Policy Research, No. 2, June 2011, www.aei.org/docLib/REG-2011-02-g.pdf
50. Arthur Fraas and Randall Lutter, “Can a Stew of Power Generation Regulations Clear the Air?” *Resources*, Resources for the Future, Fall 2010, No. 176, p. 30, <http://www.rff.org/Publications/Resources/Pages/Can-a-Stew-of-Power-Generation-Regulations-Clear-the-Air-176.aspx>
51. Randall Lutter, “Superior Salmon and More”, *RFF Weekly Policy Commentary*, September 27th, 2010, <http://www.rff.org/Publications/WPC/Pages/Superior-Salmon-and-More.aspx>
52. Randall Lutter and William McConagha, “The FDA Responds”, *Public Health Reports*, 2008 Jul-Aug; 123(4): 422–423,

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2430636/>

53. Begosh, Allan, John Goldsmith, Ed Hass, Randall Lutter, Clark Nardinelli, John Vernon, “Black Box Warnings and Drug Safety: Examining the Determinants and Timing of FDA Warning Labels”, *National Bureau of Economic Research Working Paper No. 12803*, December 2006, <http://www.nber.org/papers/w12803>
54. Randall Lutter, “Are There Any Cost-Effective Greenhouse Gas Controls That Politicians Would Like?” Americans for Equitable Climate Solutions. <http://aecs-inc.org>. 2003.
55. Randall Lutter and Troy Kravitz, “Do Regulations Requiring Light Trucks To Be More Fuel Efficient Make Economic Sense? An Evaluation of NHTSA’s Proposed Standards”, Regulatory Analysis 03-2, AEI-Brookings Joint Center for Regulatory Studies, at <http://aei.brookings.org/admin/pdffiles/phpsa.pdf>, February 2003.
56. Randall Lutter, “Rationalizing Air Pollution Regulation”, *Regulation*, Volume 25, No. 1, 6-7, 2002.
57. Randall Lutter and Richard Belzer, “Authors and ACACCA Agree (Mostly)”, Letter to the Editor of *Regulation*, Volume 25, No. 1, 2002.
58. Randall Lutter and Hoi Ying So, “Kyoto in Europe: Lessons for Policy Makers”, European Policy Forum, at www.epfltd.org, July 2002.
59. Randall Lutter, “CAFE-The Numbers Behind the Story”, AEI-Brookings Joint Center for Regulatory Studies, Policy Matters 02-13, <http://www.aei-brookings.org/policy/page.php?id=84>, March 2002.
60. Randall Lutter and Elizabeth Mader, “Flushing Federalism”, AEI-Brookings Joint Center for Regulatory Studies, Policy Matters 01-27, November 2001.
61. Randall Lutter and Elizabeth Mader, Letter to the Editor about “Lead in Soil: Is Your Backyard Safer than a Hazardous Waste Site” *EM Magazine*, Air and Waste Management Association, 6, November 2001.
62. Randall Lutter, “Economic Analysis of Regulation in the U.S.: What Lessons for the European Commission?” Report to the Enterprise Directorate General, European Commission, For the Workshop on Impact Assessment in Member States, Brussels, June 26, 2001. http://ec.europa.eu/enterprise/policies/better-regulation/files/study_en.pdf
63. Randall Lutter, Elizabeth Mader, and Nathan Knuffman, “Regulating Mercury Emissions: What Do We Know About Costs and Benefits?” AEI-Brookings Joint Center for Regulatory Studies, Regulatory Analysis, <http://www.aei.brookings.org> March 2001.

64. Randall Lutter and Elizabeth Mader, “Health Risks From Mercury-Contaminated Fish: A Reassessment”, AEI-Brookings Joint Center for Regulatory Studies, Related Publication, March 2001.
65. Robert W. Hahn, Randall Lutter, and W. Kip Viscusi, Do Federal Regulations Reduce Mortality? AEI-Brookings Joint Center for Regulatory Studies, Washington D.C. www.aei.brookings.org, November 2000.
66. Randall Lutter and Richard B. Belzer, “EPA Pats Itself on The Back”, *Regulation*, Volume 23, No. 3, 23-28, 2000.
67. Randall Lutter, “Will the Supreme Court Clear the Air?” (November 2000), American Enterprise Institute and AEI-Brookings Joint Center for Regulatory Studies, Policy Matters Working Paper No. 00-17. Available at SSRN: <http://ssrn.com/abstract=259789>
68. Nathan Knuffman and Randall Lutter, “Does Mercury in Fish Come from the Air?” AEI-Brookings Joint Center for Regulatory Studies, AEI-Brookings Joint Center for Regulatory Studies, Working Paper 00-06, September 2000.
69. Randall Lutter, “Valuing Children’s Health: A Reassessment of the Benefits of Lower Lead Levels”, AEI-Brookings Joint Center for Regulatory Studies, Working Paper 00-02, March 2000.
70. Randall Lutter, “Is EPA’s Ozone Standard Feasible?” AEI-Brookings Joint Center for Regulatory Studies, Regulatory Analysis 99-6, 1999.
71. Randall Lutter, “An Analysis of the U.S. Department of Agriculture’s Proposal to Allow Irradiation of Meat”, AEI-Brookings Joint Center for Regulatory Studies, Regulatory Analysis 99-2, July 1999.
72. Randall Lutter, “The Role of Economic Analysis in Regulatory Reform”, *Regulation*, Volume 22, No. 2, 38-46, 1999. <https://www.cato.org/pubs/regulation/regv22n2/econanalysis.pdf>
73. Randall Lutter and Christopher DeMuth, “Wizards of Ozone”, *The Weekly Standard*, 17-19, June 21, 1999. This article also appeared in *On the Issues*, American Enterprise Institute for Public Policy Research, www.aei.org, July 1999.
74. Randall Lutter, “An Analysis of the Use of EPA’s Clean Air Benefit Estimates in OMB’s Draft Report on the Costs and Benefits of Regulation”, AEI-Brookings Joint Center for Regulatory Studies, Comment 98-2, October 1998.

Testimony

1. Arthur Fraas and Randall Lutter, Comment on the U.S. Office of Management and Budget, on Interim OMB Guidance Implementing the January 30th, 2017 Presidential Executive Order on Reducing Regulation and Controlling Regulatory Costs. February 10, 2017
2. Randall Lutter, Perspectives on Retrospective Review and Analysis, Testimony for the House Committee on the Judiciary, Subcommittee on Courts, Commercial and Administrative Law, Clearing the Way for Jobs and Growth: Retrospective Review to Reduce Red Tape and Regulations, July 12, 2012.
3. Joe Aldy, Art Fraas and Randall Lutter, Public Interest Comment on The Office of Management and Budget's Draft 2012 Report to Congress on the Benefits and Costs of Federal Regulations, June 2012
4. Randall Lutter, "Environmental Regulation, the Economy and Jobs", Testimony Before the Energy and Commerce Committee Subcommittee on Environment and the Economy, February 15, 2011. <http://www.rff.org/RFF/Documents/RFF-CTst-Lutter-Feb152011.pdf>
5. Randall Lutter, "Agencies' Regulatory Analyses Should Be Subject to Genuinely Independent Peer-Review," Testimony Before The Water Resources and Environment Subcommittee of the House Transportation and Infrastructure Committee, Hearing on Independent Peer-Review of Scientific, Technical and Economic Products that Support Agency Decision-Making, March 5, 2003.
<http://aei.brookings.org/publications/abstract.php?pid=315>
6. Randall Lutter and Elisabeth Irwin, "FDA Should Allow Food Labeling Claims About Nutrient Content and Health", to the Food and Drug Administration, AEI-Brookings Joint Center for Regulatory Studies, Testimony 02-8, September 2002.
<http://aei.brookings.org/admin/pdf/files/phpUe.pdf>
7. Randall Lutter, "Improving Regulatory Analysis at the Environmental Protection Agency", Testimony Before the House Committee on Small Business, Subcommittee on Regulatory Reform and Oversight, November 2001.
www.aei.brookings.org/publications/testimony/testimony_01_05.pdf
8. Robert W. Hahn and Randall Lutter, "Elevating EPA to Cabinet Status", Testimony before the House Committee on Government Reform, Subcommittee on Energy Policy, Natural Resources, and Regulatory Affairs, September 2001.
www.aei.brookings.org/publications/testimony/testimony_01_04.pdf

Professional Experience

Professor of Public Policy, Frank Batten School of Leadership and Public Policy, University of Virginia, August 2013 to the present. Served as Senior Lecturer from August 2013 to December 2015.

- Principal Investigator, The Economic Value of Improvements in Cognitive Performance Attributable to Breastfeeding, The Bill and Melinda Gates Foundation, April 2015 through December 2017. \$724,000 in original funding and \$145,000 in supplemental funding.
- Teaches graduate courses in
 - benefit-cost analysis
 - environmental and natural resource policy
 - federal regulatory policy
 - data analysis and statistics
- Supervises applied public policy projects for candidates for Master of Public Policy.

Visiting Fellow, Resources for the Future, Washington, D.C, May 2010 to the present.

- Co-principal Investigator, with Richard Morgenstern and Art Fraas, Regulatory Performance Initiative, Sloan Foundation and Smith Richardson Foundation. \$584,000. <http://www.rff.org/research/collection/regulatory-performance-initiative-rff>. In its 2015 annual report to Congress on the benefits and costs of federal regulation, the Office of Management and Budget cited this work and encouraged federal agencies to consider whether these analyses have identified any regulations that might be good candidates to retrospectively review.
- Organizer, moderator and speaker for February 19th, 2013 symposium on agricultural biotech and the environment. For video and selected slides, see <http://www.rff.org/Events/Pages/Agricultural-Biotechnology-and-the-Environment.aspx>.
- With Art Fraas, co-organizer, moderator and speaker for April 7th, 2011, conference “Can Greater Use of Economic Analysis Improve Regulatory Policy at Independent Regulatory Commissions?” <http://www.rff.org/Events/Pages/Can-Greater-Use-of-Economic-Analysis-Improve-Regulatory-Policy-at-Independent-Regulatory-Agencies.aspx>, supported by the Ewing Marion Kauffman Foundation.

Independent consultant and economist, Bethesda, MD, January 2010 to the present.

- Conducts analysis of regulatory issues for corporate and nonprofit organizations.
- Trains government officials for the U.S. and other countries.
- Chaired CropLife America Science Forums on judging the quality of scientific work (May 2011) and on judging weight of evidence approaches (May 2012).

Senior Economist, Office of Information and Regulatory Affairs, Office of Management and Budget. September 2009 to January 2010. Advised the OIRA Administrator, conducted economic analysis in support of regulatory review.

Deputy Commissioner for Policy, FDA, January 2007 to August 2009. Responsible for coordinating the development and issuance of FDA regulations and guidance documents. Directed development of strategic policy and planning, focusing on performance. Played a lead role articulating FDA's concerns about the risks of importation of unapproved pharmaceutical products. Co-chaired the FDA's Counterfeit Drug Task Force and FDA's Nanotechnology Task Force.

- Responsible for supervision of the Offices of Policy and Planning, Counterterrorism and Emerging Threats, and Advisory Committee Oversight and Management. Supervised nearly 90 staff including lawyers, medical officers, pharmacists, economists, statisticians and operations research analysts involved in the development of science-based regulatory policies and performance-based planning.
- Led development of new policies addressing consumer safety, covering safety of food from animal clones, genetically engineered animals, risk of BSE from animal feed, and risk of salmonella from shell eggs.
- Oversaw policy analysis for new legislative proposals, including user fee programs for drugs and medical devices.
- Initiated and engineered a new effort to anticipate and prevent economically-motivated adulteration of foods and drugs, by applying an economics paradigm to such adulteration. <http://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm163619.htm>
- Led development of new policies on advisory committees including more stringent standards for granting waivers of conflicts of interest, more transparency in disclosure of such waivers, and more timely posting of briefing materials to the public <http://www.fda.gov/oc/advisory/aclawsregs.html>
 - Designed and oversaw studies showing greater expertise is provided by advisory committee members who need waivers for conflicts of interest <http://www.fda.gov/oc/advisory/ERGCOIreport.pdf>, and that there is no correlation between having such conflicts when duly disclosed and voting patterns <http://www.fda.gov/oc/advisory/conflictinterest/ERGCOIAndVoting011509.pdf>
- Promoted preparedness by authorizing the emergency use of doxycycline hyclate tablet emergency kits for the post-exposure prophylaxis of anthrax for eligible US Postal Service participants and their household members.
- Testified before Congress, including on drug importation, <http://www.fda.gov/ola/2007/importdrugs30707.html> and federal preemption of state law <http://oversight.house.gov/documents/20080514142253.pdf>

Associate Commissioner for Policy and Planning, Food and Drug Administration. Led and directed policy and planning staff with expertise in law, microbiology, pharmacy, economics, statistics and operations research. April 2005 to January 2007.

- Led effort to implement pedigree requirements to fight counterfeit drugs. http://www.fda.gov/oc/initiatives/counterfeit/report6_06.html

- Designed and led analysis of confusing foreign drug names, resulting in first-of-a-kind public health advisory that consumers filling prescriptions abroad may get the wrong active ingredient. <http://www.fda.gov/oc/opacom/reports/confusingnames.html>
- Helped design studies to detect and assess risks to consumers of imported unapproved drug products found at international mail facilities and articulated the results of such studies to the press. <http://www.fda.gov/bbs/topics/NEWS/2005/NEW01277.html>
- Warned governors and mayors about the risks associated with programs to import unapproved foreign drugs.

Chief Economist, Office of Planning, Office of Policy and Planning, Food and Drug Administration. Responsible for ensuring that all FDA proposed and final regulations, prior to publication in the Federal Register, comply with Executive Order 12866, all relevant directives and requirements from the Office of Management and Budget (including the OMB guidance on economic analysis), the Regulatory Flexibility Act and the Unfunded Mandates Reform Act. Ensured analysis supporting such policy-related regulatory decisions conforms to these administrative and legal requirements. March 2003 to April 2005.

- Won FDA Commissioner's Award for Excellence, 2004.
- Conducted and directed economic analyses of FDA regulatory issues and supervised and directed the work of the economics staff to ensure completion of economic analyses was timely and could inform leadership before relevant risk management decisions.
- Directed analysis of the economic effects of the legalization of commercial drug importation for the Department of Health and Human Services Task Force on Drug Importation. <http://archive.hhs.gov/importtaskforce/Report1220.pdf>. Negotiated \$400,000 in funding for this report from the Department of Commerce and the Assistant Secretary of Planning and Evaluation of the Department of Health and Human Services.
- Led FDA technical team advising the Department of Commerce on study of the effects of foreign price controls on pharmaceutical research and development for a report to Congress.
- Co-chaired interagency group advising OMB about its guidance to regulatory agencies on the conduct of economic analysis.

Resident Scholar at the American Enterprise Institute and *Fellow* with the AEI-Brookings Joint Center for Regulatory Studies. Researched benefits and costs of ongoing health, safety and environmental regulatory initiatives, and methods of evaluating regulatory effects. Areas of specialization ranged from food safety and labeling, to air pollution, global warming and toxic

substances, and regulatory reform. August 1998 to March 2003.

Senior Economist for the environment and regulation, the President's Council of Economic Advisers, Executive Office of the President. July 1997 - August 1998.

- Analyzed economic effects of limiting greenhouse gas emissions and different arrangements for international trade in emission permits. Helped draft key Congressional testimony on the Kyoto Protocol. Initiated proposals for developing countries to accept indexed greenhouse gas emissions targets. Presented results to top officials from the White House and Cabinet agencies.
- Analyzed electricity restructuring proposals, especially environmental policies to limit air pollutant emissions. Reviewed and critiqued key environmental regulations. Developed recommendations for members of the Council and other top White House officials.
- Analyzed major air pollution regulations and persuaded decision-makers to adopt more efficient regulatory alternatives.
- Chaired interagency group on methods of analyzing costs and benefits of federal regulations.
- Authored parts of the *Economic Report of the President 1998* and wrote several weekly economic briefings for the President.

Staff Economist for the Office of Information and Regulatory Affairs, Office of Management and Budget, Executive Office of the President. Summarized and justified alternative policy recommendations to White House and OMB decision-makers, giving special emphasis to market-based alternatives to traditional command and control regulations. Helped write guidance to Federal agencies on how to conduct benefit-cost analysis. Completed executive training for Senior Executive Service. September 1991 - July 1997.

- Earned OMB Exceptional Achievement Award 1996, OMB Professional Achievement Awards, 1993, 1995.
- Staffed President Clinton's Health Care Reform Task Force and provided briefings to the Cabinet and the President about the effects of price controls.
- Drafted sections of OMB's 1996 best practices document on economic analysis of federal regulations under Executive Order 12866. http://www.whitehouse.gov/omb/inforeg_riaguide
- Served as lead OMB analyst for major regulations and policy initiatives including
 - EPA's 1997 air quality standards for ozone and particulate matter
 - EPA's drinking water standards
 - USDA's EQIP and Conservation Reserve Program
 - FDA's food labeling regulations
 - FDA's tobacco regulation
 - EPA's control of toxic substances (PCBs, lead, and pesticides).

Adjunct Professor, Department of Economics, American University. Taught economics of health care and health policy. Spring, 1995.

Assistant Professor of Managerial Economics and Policy, School of Management, State University of New York at Buffalo. Advised and instructed doctoral candidates, MBA candidates, and mid-career managers. Developed courses in international economics for MBA students and seminars for mid-level managers. Taught managerial economics, applied macro-economics and corporate finance. 1985 – 1991.

- Best Instructor of the Year, School of Management, 1986-1987.

Associate Director for the USAID-funded Institute for the Study of Free Enterprise Systems at the State University of New York at Buffalo. Planned, organized scholarly conferences, wrote periodic performance reports, prepared annual budgets, supervised research assistants. 1987 – 1991.

Economic Development Consultant, U.S. Embassy, Yaounde, Cameroon. Identified locally initiated community development projects in the Republic of Equatorial Guinea, and evaluated their suitability to receive funding from the Self-Help program of the U.S. Embassy. 1980.

Staff, Peace Corps, Cameroon. Responsible for support and administration of cooperative assistance program. Assessed feasibility and desirability of establishing Peace Corps program in the Republic of Equatorial Guinea. 1980.

Management Advisor, cocoa marketing cooperative, Peace Corps, Cameroon. As Peace Corps volunteer, designed and implemented systems for cocoa marketing, cash and produce control. Performed and supervised internal audits, assisted audits by the supervisory ministry. Provided training to cooperative staff and officials. 1978-1980.

Additional Activities

Selected Presentations

Randall Lutter, “Benefit-Cost Analysis at the Office of Information and Regulatory Affairs: Perspectives of a Practitioner”, Workshop at the Annual Meetings of the Society for Benefit-Cost Analysis. March 2016. Washington D.C.

Randall Lutter, “The Use of Science at FDA”, January 2016, Searle Civil Justice Institute Conference, “Regulatory Daubert: An Examination of the Issues”, George Mason University Law School, Arlington VA.

Randall Lutter, “Genetically Engineered Organisms: Perspectives of a Former Regulator”, November 2015, invited presentation at “FDA Premarket Approval and the Future of Innovation, Institute for Humane Studies & Mercatus Center, George Mason University, New Orleans, November 20th, 2015.

Art Fraas and Randall Lutter, “PM Benefits Estimates, Sans Uncertainty”, presented at

the annual meetings of the Society for Benefit Cost Analysis, February 2013, Washington D.C.

Randall Lutter, “Regulations and Jobs, An Economist’s Views”, presented at the annual meetings of the Administrative Law Section of the American Bar Association, November 2010, Washington D.C.

Randall Lutter, “Improving Food Safety: How Best to Quantify Public Health Agencies’ Performance Responding to Outbreaks of Foodborne Illness?” American Society of Health Economists, Cornell University, June 2010.

Randall Lutter, “Regulatory Oversight and Productivity in Pharmaceutical Innovation: A Perspective from FDA”, American Society of Health Economists, Duke University, June 2008.

Randall Lutter, “New Perspectives on Pharmaceutical Innovation”, American Society of Health Economists, Duke University, June 2008.

Randall Lutter, “The Wrongful Segregation of Risk Assessment and Benefit-Cost Analysis”, Society for Risk Analysis, New Orleans, December 2002.

Randall Lutter, “Improving RIA Quality: Insights from the U.S.” APEC-OECD Co-operative Initiative on Regulatory Reform. Merida, Mexico, April 2002.

Randall Lutter, “CAFE After 9/11”, Society of Automotive Analysts, Detroit, January 8, 2002.

Arthur Fraas and Randall Lutter, “Regulatory Analysis: Past Experience with EPA Analysis and New Challenges”, presented at the annual meeting of the *Southern Economic Association*, Washington D.C., 1996.

Randall Lutter, “Distributional Effects of Selected Environmental Regulations”, presented at the annual meeting of the *Southern Economic Association*, Washington D.C., November 1996.

Randall Lutter, “Allocative Inefficiencies of State Owned Enterprises in Imperfectly Competitive Markets: Evidence from Air Transport,” presented at the *American Economics Association* meetings, January 1992.

Selected General Interest Articles and Appearances

Randall Lutter, “Developments in Federal Regulatory Policy”, the Committee for Economic Development, March 15, 2017. Committee for Economic Development

Randall Lutter
CV

Randall Lutter, “The Future of Genome Editing and How It Will be Regulated”, Interview with UVAToday, January 26, 2017, https://www.news.virginia.edu/content/qa-future-genome-editing-and-how-it-will-be-regulated?utm_source=DailyReport&utm_medium=email&utm_campaign=news

Randall Lutter, “What Would Madison Think? New federal regulations in the pipeline prior to November”, Batten Reports, Fall 2016. Frank Batten School of Leadership and Public Policy, UVa. <http://batten.virginia.edu/school/news/federal-regulatory-policy-2016-would-madison-approve>

Susan E. Dudley, Art Fraas, Ted Gayer, John Graham, Randall Lutter, Jason F. Shogren, W. Kip Viscusi, “How Much Will Climate Change Rules Benefit Americans?” *Forbes, / Opinion*, February 9, 2016. <http://www.forbes.com/sites/susandudley/2016/02/09/how-much-will-climate-change-rules-benefit-americans/#99f493c59ec7>

Art Fraas and Randall Lutter, “Rulemaking Negligence at EPA”, *Washington Times*, October 2013. <http://www.washingtontimes.com/news/2013/oct/6/fraas-and-lutter-rule-making-negligence-at-the-epa/>

Joe Aldy, Art Fraas and Randall Lutter, “Financial Regulation Sans Analysis”, *Politico*, June 21, 2012, www.politico.com/news/stories/0612/77644.html

Randall Lutter, “Building Carbon Emissions Markets”, Panel Discussion on Policy Options for Power Plant Multi-Emission Control Legislation, Americans for Equitable Climate Change Solutions, December 10th, 2002.

Randall Lutter, “‘Gone Fishin’ For Nutrition’ Misses an Important Point”, Letter to the Health Editor, *Washington Post*, November 26, 2002.

Randall Lutter, “FDA Squashes Fish Tales”, *Washington Times*, <http://www.washtimes.com/commentary/20021029-84262998.htm>, October 29, 2002.

Randall Lutter, “What Grade for Government Regulations?” Administrative Law Section of the American Bar Association, Washington D.C., October 2002.

Randall Lutter, “Litigating Lead Hazards: Is it a Solution?” at conference on “Finding Effective Solutions for Lead Base Paint Hazards”, Center for Legal Policy Forum of the Manhattan Institute for Policy Research, Providence, R.I., June 19th, 2002.

Randall Lutter, “Clean Air and Polluted Science”, *Washington Times*, March 25, 2002, also *On the Issues*, American Enterprise Institute, and AEI-Brookings Joint Center for Regulatory Studies, *Policy Matters 02-12*, March 2002.

Randall Lutter, “Bountiful Incentives”, Tech Central Station At <http://www.techcentralstation.com>, March 2002.

Randall Lutter, “Rationalizing Air Pollution Regulation”, Presentation at conference *Regulating Air Pollutants from Power Plants: What is Sensible?* by the AEI-Brookings Joint Center for Regulatory Studies. February 19th, 2002.

Randall Lutter, “How to Get Clean Air At Less Cost”, *Washington Times*, February 5th 2002, also *On the Issues*, American Enterprise Institute, and AEI-Brookings Joint Center for Regulatory Studies, *Policy Matters 02-6*, February 2002.

Randall Lutter, “Put a Price on His Head”, Tech Central Station At <http://www.techcentralstation.com/DefenseExtra.asp?id=160>, January 2002, also *On the Issues*, American Enterprise Institute

Randall Lutter, Radio interview on global warming with The Voice of America, December 18, 2001.

Randall Lutter, “Refining Repairs to Regulatory Reform”, Presentation to the Weidenbaum Center Forum “Executive Regulatory Review: Surveying the Record, Making it Work”, National Press Club, Washington, D.C., December 17, 2001.

Randall Lutter, “Litigating Lead Hazards: Is it a Solution?” at conference on “Finding Effective Solutions for Lead Base Paint Hazards”, Center for Legal Policy Forum of the Manhattan Institute for Policy Research, Baltimore, December 13, 2001.

Randall Lutter, “Chill Out on Warming” in German, *Financial Times Deutschland*, April 10, 2001.

Randall Lutter, “Ignoring All Costs Won’t Clean Our Air”, *Los Angeles Times*, March 5, 2001.

Randall Lutter, The Benefits and Costs of Regulating Mercury Emissions From Utilities, Presentation at Resources for the Future, January 17, 2001.

Randall Lutter, Heather Ross and John Fialka, Videotaped panel discussion for the *National Economists Club Education Foundation*, “Air Quality Costs and Benefits: In Economics and the Law”, January 10, 2001.

Randall Lutter, Interview on the Supreme Court’s review of the Environmental Protection Agency’s 1997 air quality standards, *National Public Radio*, Salt Lake City, November 14, 2000.

Randall Lutter, “Costs Swamp Benefits”, *Los Angeles Times*, November 7, 2000.

Randall Lutter, "Clouds on the Open Sky Horizon", *Washington Times*, A2, June 12, 2000.

Randall Lutter, Interview on food irradiation for *Newsnight* Maryland Public Television, May 30, 2000.

Randall Lutter, "Irradiation: Almost Perfect", *Washington Post*, April 4, 2000.

Education

Degrees:

Ph.D. Economics, Cornell University, 1986

M.A. Economics, Cornell University, 1983

B.A. Economics, University of California, Berkeley, 1977: Phi Beta Kappa

Languages: Fluent French, conversational Spanish

Service

Lectures / Presentations / Seminars given at: American Bar Association, American Economic Association, American Enterprise Institute, Americans for Equitable Climate Solutions, American University, American Water Works Association, Boston University, Brookings, College of William and Mary, Consumer Financial Protection Bureau, Cornell University, Duke University, Eastern Finance Association, European Association for Research in Industrial Economics, European Commission (Enterprise DG), Food and Drug Administration (CFSAN), George Washington University, Harvard University (Kennedy School), Michigan State University, National Economists Club, National Economists Club Education Foundation, Resources for the Future, Society for Benefit-Cost Analysis, Society of Government Economists, Society for Risk Analysis, Southern Economics Association, State University of New York at Buffalo, University of Delaware, University of Maryland, University of Maryland Baltimore County, University of Minnesota, University of Virginia (Law School), University of Wyoming, U.S. Department of Agriculture (Economic Research Service), Western Economics Association, the World Bank.

Referee for: American Enterprise Institute, AEI-Brookings Joint Center for Regulatory Studies, *American Economic Review*, *American Journal of Public Health*, Brookings, Congressional Budget Office, *Economic Inquiry*, *Energy Journal*, *International Journal of Industrial Organization*, *Journal of Air and Waste Management*, *Journal of Benefit-Cost Analysis*, *Journal of Environmental Economics and Management*, *Journal of Health Economics*, *Journal of Industrial Economics*, *Journal of Risk and Uncertainty*, *Mercatus Center*, National Research Council, NBER, Office of Management and Budget, *Operations Research*, *Management Science*, Prentice-Hall, *Regulation and Governance*, Smith-Richardson Foundation, the World Bank.

Leadership in Professional Societies: Society for Benefit-Cost Analysis, Assistant Treasurer 2015, Treasurer 2016, Past Treasurer 2017.

Personal Interests: Whitewater kayaking (Over-the-Falls Race, Ohiopyle, PA, 2007-2009, 2012, and 2015, www.fallsrace.com; Cheat River Race 2008, 2010-15 <http://www.cheatriverrace.com/> and Potomac Downriver Race 2009 and 2010, and 2015, 2nd place, Potomac Little Falls Race, 2016); event chair for the 2010 USA Canoe Kayak National Slalom Championships at Mirant's Dickerson Station; 2011-2014, secretary of Potomac Whitewater Racing Center, <http://bce-racing.com/blog/> 2010-2013.