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**Randall Lutter, Ph.D.**  
Senior Fellow, Manhattan Institute

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Randall Lutter, Ph.D., is Senior Fellow at the Manhattan Institute where he writes about federal regulation, medical innovation, public health and pharmaceutical markets. He has more than 30 years of experience in the analysis and management of federal programs to protect health, safety and the environment. He has served at the Food and Drug Administration in multiple roles including Deputy Commissioner for Policy. He previously served as senior economist at the federal Office of Management and Budget, and as senior economist for regulation and the environment at the President's Council of Economic Advisers. Dr. Lutter taught at the Frank Batten School of Leadership and Public Policy at the University of Virginia, and was visiting scholar at Resources for the Future. He was resident scholar at the American Enterprise Institute and fellow at the AEI-Brookings Joint Center for Regulatory Studies. He taught economics at the State University of New York at Buffalo after earning a Ph.D. in economics from Cornell University. He has authored or co-authored more than 75 technical and policy papers. His research has appeared in the *American Economic Review*, *Environmental Science & Technology*, *Journal of Political Economy*, and *Science*, and his writing is in *National Review*, *Politico*, *Regulation*, and *The Hill*.

**Selected Research Papers (Peer-reviewed work is in bold).**

Research papers categories are medical product regulation; nutrition, food safety and health; energy and the environment; benefit-cost analysis; and other.

I. Medical Product Regulation

1. Andrew von Eschenbach, Stephen Ostroff, David Acheson, Dan Troy, Kalah Auchincloss, Randall Lutter, Patrick Ronan, Cynthia Schnedar. Brief Amici Curiae to the Supreme Court of the United States, Johnson & Johnson et al., Petitioners, v. Mississippi ex rel. Lynn Fitch, Attorney General of Mississippi, *On Petition for Writ of Certiorari to the Supreme Court of Mississippi*, October 2021, No. 21-348,
2. Carolyn Wolff and Randall Lutter, 2020, "[\*\*Why are Pharmacy Acquisition Costs and Consumer Prescription Drug Price Indices Apparently Diverging?\*\*](#)" *Health Economics*. 29(12):1721-1727, December, 2020
3. Lubna Merchant, Randall Lutter, and Sherry Chang, 2020, "Identical or Similar Brand Names Used in Different Countries for Medications With Drug Different Active Ingredients: A Descriptive Analysis", *British Medical Journal: Quality and Safety*, 0:1-4. Doi:10.1136/bmjqs-2019-010316
4. Ryan Conrad and Randall Lutter, 2019, "[Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices](#)", U.S. FDA, Center for Drug Evaluation and Research,
5. Ryan Conrad, William Liu, Zachary Tillman, Alvin So, Andreas Schick, Clark Nardinelli, Randall Lutter, 2018, [Estimating Cost Savings From Generic Drug](#)

6. [Approvals in 2017](#), U.S. FDA, Center For Drug Evaluation and Research,
7. Randall Lutter and David Zorn, 2016, “Improving Regulatory Cooperation Between the FDA and the EU”, Report for the George Washington University Regulatory Studies Center Published as part of a series on [US-EU Regulatory Cooperation: Lessons and Opportunities](#). Presented to the EU Delegation to the U.S., September 15<sup>th</sup>, 2016.
8. Randall Lutter, “[Herding Genetically Engineered Animals to Market](#)”, Resources for the Future Blogpost, December 16<sup>th</sup>, 2015
9. Randall Lutter, 2013, Letter: “Waiving Concerns About Conflicts of Interest”, *Science*, 341:1173.
10. Randall Lutter, “[Superior Salmon and More](#)”, 2010, *RFF Weekly Policy Commentary*
11. **Vernon, John A., Joseph Golec, Randall Lutter, and Clark Nardinelli, 2009, “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, 1260-1274.**
12. **Randall Lutter and William McConagha, 2008, “[The FDA Responds](#)”, *Public Health Reports*, 123(4): 422–423**
13. **McWilliam, Andrew, Randall Lutter and Clark Nardinelli, 2008, “Healthcare Impact of Personalized Medicine Using Genetic Testing: An Exploratory Analysis for Warfarin”, *Personalized Medicine*, 5(3), 279-284.**
14. Begosh, Allan, John Goldsmith, Ed Hass, Randall Lutter, Clark Nardinelli, John Vernon, 2006, “Black Box Warnings and Drug Safety: Examining the Determinants and Timing of FDA Warning Labels”, *National Bureau of Economic Research Working Paper No. 12803*, <http://www.nber.org/papers/w12803>

## II. Health, Nutrition and Food Safety

1. Randall Lutter, Spring 2023, [Allowing Slaughter-Free Meat](#), *Regulation*
2. Randall Lutter, February 2023, Letter: [Federal Journals Need Transparency Policies](#), *Science*, 379(6634) 766-767
3. Randall Lutter, January 2023, [Are Research Papers Published in Federal Health Journals Independently Reproducible?](#) Manhattan Institute Issue Brief
4. Randall Lutter, September 2022, [CDC’s COVID-19 Communication Failures: Reforming the Process for Public Health Recommendations](#), Manhattan Institute Issue Brief
5. Randall Lutter, May 5, 2022, [Fighting Fentanyl: The Biden Administration’s Failure of Leadership](#). Issue Brief, Manhattan Institute.
6. Randall Lutter, September 16, 2021, [Pandemic Preparedness: What Role for the Private Sector?](#) Manhattan Institute Issue Brief
7. **Randall Lutter, Christopher J. Ruhm, Dajun Lin and Siying Liu, 2018, “[Does Breastfeeding Duration Predict Schooling and Income? Insights from the Indonesian Family Life Survey](#)”, *Maternal and Child Nutrition*, April 20<sup>th</sup>, 2018.**
8. **Arindam Nandi, Randall Lutter and Ramanan Laxminarayan, 2017, “Breastfeeding Duration and Adolescent Educational Outcomes: Longitudinal Evidence from India”, *Food and Nutrition Bulletin*, Vol 38, No. 4,**

- <http://journals.sagepub.com/doi/10.1177/0379572117733100>
9. Abigail Colson, Roger Cooke and Randall Lutter, 2016, “How Does Breastfeeding Affect IQ? Applying the Classic Model of Structured Expert Judgment”, Resources for the Future Discussion Paper 16-28
  10. Marc Hafstead and Randall Lutter, 2016, “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.
  11. Randall Lutter, 2015, “How Effective Are Federal Food Safety Regulations? The Case of Eggs and *Salmonella* Enteritidis”, RFF Discussion Paper 15-24, <http://www.rff.org/Publications/Pages/PublicationDetails.aspx?PublicationID=22570>. Featured in <http://www.rff.org/events/event/2015-10/real-outcomes-federal-environmental-regulations-lessons-performance-data>
  12. **Randall Lutter, 2014, “A Bounding Analysis of the Benefits of Reducing Perchlorate Concentrations in Drinking Water”, *Risk Analysis*; 34(10):1944-56.**
  13. **Chessa Lutter and Randall Lutter, 2012, “[Fetal and Early Childhood Undernutrition, Mortality and Lifelong Health](#)”, *Science*, 337:1495-99.**
  14. 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,
  15. **Randall Lutter and Katherine Tucker, 2003, “[Unacknowledged Health Benefits of Genetically Modified Food: Salmon and Heart Disease Deaths](#),” *AgBioForum*, 5(2), 59-64,**
  16. **Randall Lutter, 1999, “Food Irradiation: The Forgotten Solution to Food-Borne Illness”, *Science*, Vol. 286, 2275-2276.**

### III. Energy and the Environment

1. Arthur Fraas, John D. Graham, Kerry Krutilla, Randall Lutter, Jason Shogren, Linda Thunström, W. Kip Viscusi, Challenges in Estimating the Social Cost of Greenhouse Gases: The Case of EPA’s New Proposed Estimates, May 2023. Manuscript
2. Arthur Fraas, Randall Lutter, Joshua Murphy, Qinrui Xiahou, Jeff Potter and Samuel Gosling, 2023, Effects of Early Childhood Exposure to Airborne Lead and Particulate Matter on Adult Personality. Forthcoming, Resources for the Future Working Paper.
3. **Arthur G. Fraas, Randall W. Lutter and Derek C. Wietelman, 2019, “The Energy Paradox in Seemingly Competitive Industries: The Use of Energy-Efficient Equipment on Heavy-Duty Truck Trailers”, *Energy Policy*, vol 129 467-480 <https://doi.org/10.1016/j.enpol.2019.01.048>**
4. Art Fraas, Randall Lutter, Susan Dudley, Ted Gayer, John Graham, Jason F. Shogren, W. Kip Viscusi, 2016, Letter: “[Social Cost of Carbon: Domestic Duty](#)”, *Science*, 05: Vol. 351, Issue 6273, pp. 569 DOI: 10.1126/science.351.6273.569-b
5. **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* 16 Dec 2014 DOI: 10.1111/risa.12277.**
6. Art Fraas and Randall Lutter, 2014, “[How Much Would EPA’s Greenhouse Gas Rule](#)

- [Cool the Earth?](#)” *Regulation*, Winter 2014-15, 4-5.
7. Art Fraas and Randall Lutter, 2013, “Review of *Using Marginal Damages in Air Pollution Policy: a Study of Air Pollution in the United States*, by Muller and Mendelsohn”, Book Reviews. *Journal of Economic Literature*, 51 (2): 572-73.
  8. **Art Fraas and Randall Lutter, 2012, “Uncertain Benefits Estimates for Reductions in Fine Particle Concentrations”, *Risk Analysis* August 2012. DOI: 10.1111/j.1539-6924.2012.01883.x** 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
  9. **Art Fraas and Randall Lutter, 2012, "[Efficient Pollution Regulation: Getting the Prices Right: Comment,](#)" *American Economic Review*, 102(1): 602–07. DOI:10.1257/aer.102.1.602**
  10. Nathan Richardson and Randall Lutter, “Making Sense of Ozone”, RFF Policy Commentary, September 19, 2011.
  11. **Art Fraas and Randall Lutter, 2011, “[Do Some NOx Emissions Have Negative Environmental Damages? Evidence and Implications for Policy](#)”, *Environmental Science & Technology*, Vol. 45, No.17**
  12. 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
  13. Randall Lutter and Jason F. Shogren, editors, 2004, *Painting the White House Green: Rationalizing Environmental Policy Inside the Executive Office of the President*, RFF Press.
  14. Randall Lutter, 2004, “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*, RFF Press.
  15. Randall Lutter, 2003, “Are There Any Cost-Effective Greenhouse Gas Controls That Politicians Would Like?” Americans for Equitable Climate Solutions.
  16. **Randall Lutter and Elisabeth Irwin, 2002, “Mercury in the Environment: A Volatile Problem”, *Environment: Science and Policy for Sustainable Development*, Vol. 44, Number 9, 24-40**
  17. Randall Lutter, 2002, “Rationalizing Air Pollution Regulation”, *Regulation*, Volume 25, No. 1, 6-7.
  18. Randall Lutter and Dallas Burtraw, 2002, “[Cleaning Air for Less: Exploiting Tradeoffs Between Different Air Pollutants](#)”, 13 *Fordham Env'tl. L. Rev.* 555.
  19. Randall Lutter and Richard Belzer, 2002, “Authors and ACACCA Agree (Mostly)”, Letter to the Editor, *Regulation*, Volume 25, No. 1.
  20. Randall Lutter and Hoi Ying So, 2002, “Kyoto in Europe: Lessons for Policy Makers”, European Policy Forum.
  21. **Randall Lutter and Jason F. Shogren, 2002, “Tradable Permit Tariffs: How Local Air Pollution Affects Carbon Emissions Permit Trading”, *Land Economics*, Vol. 78, No. 2, 159-170.**
  22. Randall Lutter and Elizabeth Mader, 2002, “Litigating Lead-Based Paint Hazards: Is

- It a Solution?” in Regulation through Litigation, Kip Viscusi, ed., AEI-Brookings Joint Center for Regulatory Studies.
23. Randall Lutter, 2001, “Sovereignty, Federalism, and the Identification of Local Environmental Problems,” *Chicago Journal of International Law*, Vol. 2, No. 2. 447-457.
  24. Randall Lutter and Elizabeth Mader, 2001, Letter to the Editor about “Lead in Soil: Is Your Backyard Safer than a Hazardous Waste Site” EM Magazine, Air and Waste Management Association.
  25. **Randall Lutter and Elizabeth Mader, 2001, “Lead in Soil: Is Your Backyard Safer Than a Hazardous Waste Site?” EM Magazine, Air and Waste Management Association, 16-21, September 2001.**
  26. **Randall Lutter, 2001, “Getting the Lead Out Cheaply: Comments on EPA’s Proposed Hazard Standards”, *Environmental Science & Policy*, Vol. 4, 13-21.**
  27. Randall Lutter and Howard Gruenspect, 2001, “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.
  28. 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.
  29. Randall Lutter and Richard B. Belzer, 2000, “EPA Pats Itself on The Back”, *Regulation*, Volume 23, No. 3, 23-28.
  30. **Randall Lutter, 2000, “Developing Countries’ Greenhouse Emissions: Uncertainty and Implications for Participation in the Kyoto Agreement”, *Energy Journal*, Vol. 21, No. 4. 93- 120.**
  31. Randall Lutter and Christopher DeMuth, “Wizards of Ozone”, *The Weekly Standard*, 17-19, June 21, 1999.
  32. Randall Lutter, 1999, “The Role of Economic Analysis in Regulatory Reform”, *Regulation*, Volume 22, No. 2, 38-46.
  33. **Randall Lutter and Christopher Wolz, 1997, “UV-B Screening by Tropospheric Ozone: Implications for the National Ambient Air Quality Standard”, *Environmental Science & Technology*, Vol. 31, 142a-146a.**
  34. **Arthur Fraas and Randall Lutter, 1996, “Abandonment of Residential Housing and the Abatement of Lead-based Paint Hazards”, *Journal of Policy Analysis and Management*, Vol. 15, 424-429, 1996.**

#### IV. Benefit-Cost Analysis and Regulation

1. **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 Linquti, Randall Lutter, Brian Mannix, Stuart Shapiro, Anne Smith, W. Kip Viscusi & Richard Zerbe, 2017, “Consumer’s Guide to Regulatory Impact Analysis: Ten Tips for Being an Informed Policymaker”, *Journal of Benefit-Cost Analysis*, July 27, 2017. 8(2), 187-204.**

doi:10.1017/bca.2017.11

2. **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. Also presented at the annual meetings of the Society for Risk Analysis, December 2013, the Society for Benefit-Cost Analysis, March 2014, and at the UVa Law School.
3. Randall Lutter and David Zorn, 2016, “On the Benefits and Costs of Public Access to Data Used to Support Federal Rulemaking”, Mercatus Center, George Mason University.
4. Randall Lutter and David Zorn, “[Reinforcing Reproducibility: What Role for the Federal Government?](#)” *Regulation*, Winter 2015-16. 15-16
5. Joe Aldy, Art Fraas and Randall Lutter, “[OMB: Obscurity in Management and Budget?](#)”, *Regulation*, Winter 2013-14, 5-6.
6. **Randall Lutter, 2013, “The Role of Retrospective Analysis and Review in Regulatory Policy,”** *Journal of Benefit-Cost Analysis*. 4(1):17-38.
7. **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.
8. **Art Fraas and Randall Lutter, 2011, “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, DOI: 10.1146/annurev-resource-083110-120042
9. Arthur Fraas and Randall Lutter, 2011, “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.
10. Randall Lutter, 2001, “[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.
11. **Randall Lutter, John F. Morrall III, and W. Kip Viscusi, 1999, “The Cost-Per-Life-Saved Cutoff for Safety-Enhancing Regulations”,** *Economic Inquiry*, Vol. 37, No. 4., 599-608.
12. **Randall Lutter and John F. Morrall, III, 1994, “Health-Health Analysis: A New Way To Evaluate Health and Safety Regulations”,** *Journal of Risk and Uncertainty*, Vol. 8, 43-66.

V. Other Research Papers

1. **Dajun Lin, Randall Lutter and Christopher J. Ruhm, 2018, “[Cognitive Performance and Labour Market Outcomes](#)”,** *Labour Economics*, vol 15, 121-

135

2. Randall Lutter, Abigail Colson, Roger M. Cooke, 2017, Effects of Increases in IQ in India on the Present Value of Earnings: A Structured Expert Judgment Study, Resources for the Future Working Paper, 17-18.
3. **Isaac Ehrlich, Georges Gallais-Hamonno, Zhiqiang Liu, and Randall Lutter, 1994, “Productivity Growth and Firm Ownership: An Analytical and Empirical Investigation,” *Journal of Political Economy*, Vol. 102, No. 5 1006–1038.**
4. **John Logan and Randall Lutter, 1989, “Guaranteed Lowest Prices: Do They Facilitate Collusion?” *Economics Letters*, Vol. 31, 189-192.**

Selected General Interest Articles and Appearances

1. Arthur Fraas, John D. Graham, Kerry Krutilla, Randall Lutter, Jason Shogren, W. Kip Viscusi, Summer 2023, Climate Damages, Globalism and Federal Regulation, forthcoming, *Regulation*, The Cato Institute
2. Randall Lutter, February 1, 2023, [Restoring Public Trust in Public Health](#), *The Hill*
3. Randall Lutter, October 2022, [Why Congress Should Step in and Regulate the CDC](#), *The Hill*
4. Charles Fain Lehman and Randall Lutter, July 5, 2022, [On Nicotine, White House Goes One Step Forward, Two Steps Back](#), *Newsweek*
5. Randall Lutter, May 17, 2022, [A Formula for Shortages](#), Eye on the News, *City Journal*
6. Randall Lutter, February 2022, [How Not to Fix Medical Supply Chains: The FDA’s Approach to Measuring Medical Shortages Obscures Vital Information](#). *City Journal*
7. John D. Graham, Art Fraas, Randall Lutter, and Jason Shogren, March 3, 2022, [“What Damages Should the Feds Consider When Regulating Carbon?”](#) *The Hill*
8. Randall Lutter, September 16, 2021, [The White House’s \\$65 Billion Pandemic Preparedness Plan Falls Short](#), *The Hill*
9. Randall Lutter, May 24, 2021, [Drug Prices are Declining Amidst Inflation Fears](#), *The Hill*
10. Arthur Fraas and Randall Lutter, April 14, 2021, [Shouldn’t Infrastructure Users Shoulder Some of the Costs?](#) *The Hill*
11. Randall Lutter, March 15, 2021 [“Watching the Regulators”](#), *National Review*
12. Randall Lutter, March 12, 2021, [Seeking COVID Vaccination](#), *RealClearHealth*
13. Randall Lutter, March 1, 2021, [EPA Dust-Up: A Recent Midnight Regulation Needs Work](#), *National Review*

14. Randall Lutter, March 15, 2017, “Developments in Federal Regulatory Policy”, Committee for Economic Development, Committee for Economic Development
15. Randall Lutter, January 26, 2017, “[The Future of Genome Editing and How It Will be Regulated](#)”, Interview with UVAToday
16. 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
17. Susan E. Dudley, Art Fraas, Ted Gayer, John Graham, Randall Lutter, Jason F. Shogren, W. Kip Viscusi, February 9, 2016, “[How Much Will Climate Change Rules Benefit Americans?](#)” Forbes, / Opinion
18. Art Fraas and Randall Lutter, October 2013, “[Rulemaking Negligence at EPA](#)”, *Washington Times*
19. Joe Aldy, Art Fraas and Randall Lutter, June 21, 2012, “[Financial Regulation Sans Analysis](#)”, *Politico*
20. Randall Lutter, December 10<sup>th</sup>, 2002, “Building Carbon Emissions Markets”, Panel Discussion on Policy Options for Power Plant Multi-Emission Control Legislation, Americans for Equitable Climate Change Solutions
21. Randall Lutter, November 26, 2002, “‘Gone Fishin’ For Nutrition’ Misses an Important Point”, Letter to the Health Editor, *Washington Post*
22. Randall Lutter, October 29, 2002, “[FDA Squashes Fish Tales](#)”, *Washington Times*
23. Randall Lutter, October 2002, “What Grade for Government Regulations?” Administrative Law Section of the American Bar Association, Washington D.C.
24. Randall Lutter, June 19<sup>th</sup>, 2002, “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.
25. Randall Lutter, March 25, 2002, “Clean Air and Polluted Science”, *Washington Times*, also *On the Issues*, American Enterprise Institute, and AEI-Brookings Joint Center for Regulatory Studies, *Policy Matters 02-12*
26. Randall Lutter, March 2002, “Bountiful Incentives”, [Tech Central Station](#)
27. Randall Lutter, February 19<sup>th</sup>, 2002, “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

28. Randall Lutter, February 5, 2002, "How to Get Clean Air At Less Cost", *Washington Times*, also *On the Issues*, American Enterprise Institute, and AEI-Brookings Joint Center for Regulatory Studies, *Policy Matters 02-6*, February 2002.
29. Randall Lutter, January 2002, "[Put a Price on His Head](#)", Tech Central Station, also *On the Issues*, American Enterprise Institute
30. Randall Lutter, December 18, 2001, "On Global Warming", The Voice of America
31. Randall Lutter, December 17, 2001, "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.
32. Randall Lutter, December 13, 2001, "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,
33. Randall Lutter, April 10, 2001, "Chill Out on Warming" in German, *Financial Times Deutschland*
34. Randall Lutter, March 5, 2001, "Ignoring All Costs Won't Clean Our Air", *Los Angeles Times*
35. Randall Lutter, Heather Ross and John Fialka, January 10, 2001. Videotaped panel discussion for the *National Economists Club Education Foundation*, "Air Quality Costs and Benefits: In Economics and the Law"
36. Randall Lutter, November 14, 2000. Interview on the Supreme Court's review of the Environmental Protection Agency's 1997 air quality standards, *National Public Radio*, Salt Lake City
37. Randall Lutter, November 7, 2000, "Costs Swamp Benefits", *Los Angeles Times*
38. Randall Lutter, June 12, 2000, "Clouds on the Open Sky Horizon", *Washington Times*, A2
39. Randall Lutter, May 30, 2000, Interview on food irradiation for *Newsnight Maryland* Public Television
40. Randall Lutter, April 4, 2000, "Irradiation: Almost Perfect", *Washington Post*

## **Work Experience**

*Senior Fellow*, Manhattan Institute, Conducts research and prepares policy briefs about pharmaceutical markets, medical product innovation and federal regulation. November 2020 to present

*Senior Science and Regulatory Advisor, Office of the Commissioner, U.S. Food and Drug Administration.* Provided the Commissioner timely state-of-the-art analysis of priority regulatory matters, including by leading projects on 1) prescription drug prices, 2) responses to the opioid crisis, 3) tobacco control policies, 4) surveillance of medical product supply chains during COVID-19. October 2017 to October 2020.

*Professor of Public Policy*, Frank Batten School of Leadership and Public Policy, University of Virginia, August 2013 to October 2017.

- Taught graduate level courses in
  - benefit-cost analysis
  - data analysis and statistics
  - environmental and natural resource policy
  - federal regulatory policy
- Supervised scores of applied public policy projects for candidates for Master of Public Policy.
- 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.

*Visiting Fellow*, Resources for the Future, Washington, D.C, May 2010 to October 2017.

- Co-principal Investigator, with Richard Morgenstern and Art Fraas, [Regulatory Performance Initiative](#), Sloan Foundation and Smith Richardson Foundation. \$584,000. In its 2015 annual report to Congress on 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 for retrospective review.
- Organizer, moderator and speaker for February 19th, 2013 [symposium on agricultural biotech and the environment](#).
- 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?](#)” supported by the Ewing Marion Kauffman Foundation.

*Independent consultant and economist*, Bethesda, MD, January 2010 to October 2017.

- Conducted economic and policy analysis of regulatory issues for large corporations and nonprofit organizations and international organizations.
- Trained government officials for the U.S. and other countries on rulemaking processes and

development of regulatory impact analyses.

- 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 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.
  - Designed and oversaw studies showing greater expertise is provided by advisory committee members who need waivers for conflicts of interest, and that there is no correlation between having such conflicts when duly disclosed and voting patterns.
- 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 policy implications of importing drugs to the U.S. (March 7, 2007), user fees and drug safety legislation (June 12, 2007), the safety of FDA-regulated imported products, (September 26, 2007), and the safety of medical products regulated by FDA (May 14, 2008).

*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.
- 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.
- 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.
- 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.

- 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. 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 foreign price and pharmaceutical research and development.
- 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. 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 major air pollution regulations and persuaded decision-makers to adopt more efficient regulatory alternatives.
- Chaired interagency group on methods of analyzing benefits and costs of federal regulations.
- Authored parts of the *Economic Report of the President 1998* and wrote periodic 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 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. September 1991 - July 1997.

- Served as analyst on 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.
- Served as lead OMB analyst for major regulations and policy initiatives including
  - EPA's 1997 air quality standards for ozone and particulate matter, drinking water standards, and control of toxic substances
  - USDA's EQIP and Conservation Reserve Program
  - FDA's food labeling regulations and tobacco regulation

*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.

*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 suitability for 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.

#### **Testimony / Public Comment to Congressional Committees or Federal Agencies**

1. Arthur Fraas, John D. Graham, Kerry Krutilla, Randall Lutter, Jason Shogren, W. Kip Viscusi, February 2023, “Comment on ‘Report on the Social Cost of Greenhouse Gases: Estimates Incorporating Recent Scientific Advances’ “, EPA Docket ID No. EPA-HQ-OAR-2021-0317.
2. Randall Lutter and Lena Lewis, June 2017, How to Regulate Genome-Edited Animals? A Comment on FDA’s Proposed Guidance, The George Washington University Regulatory Studies Center
3. Arthur Fraas and Randall Lutter, February 2017, Comment on the U.S. Office of Management and Budget, on Interim OMB Guidance Implementing the January 30<sup>th</sup>, 2017 Presidential Executive Order on Reducing Regulation and Controlling Regulatory Costs.
4. Randall Lutter, July 2012, 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.
5. Joe Aldy, Art Fraas and Randall Lutter, June 2012, Public Interest Comment on The Office of Management and Budget’s Draft 2012 Report to Congress on the Benefits and Costs of Federal Regulations,
6. Randall Lutter, February 2011, “Environmental Regulation, the Economy and Jobs”, Testimony Before the Energy and Commerce Committee Subcommittee on Environment

and the Economy. <http://www.rff.org/RFF/Documents/RFF-CTst-Lutter-Feb152011.pdf>

7. Randall Lutter, March 2003, “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.
8. Randall Lutter and Elisabeth Irwin, September 2002, “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.
9. Randall Lutter, November 2001, “Improving Regulatory Analysis at the Environmental Protection Agency”, Testimony Before the House Committee on Small Business, Subcommittee on Regulatory Reform and Oversight.
10. Robert W. Hahn and Randall Lutter, September 2001, “Elevating EPA to Cabinet Status”, Testimony before the House Committee on Government Reform, Subcommittee on Energy Policy, Natural Resources, and Regulatory Affairs.

### **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 20<sup>th</sup>, 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.

## **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 Mason University Law School, 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*, Manhattan Institute, Mercatus Center, National Research Council, NBER, Office of Management and Budget, *Operations Research*, *Management Science*, Prentice-Hall, *Regulation and Governance*, *Risk Analysis*, 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:**

Hiking and travel

Whitewater kayaking

- Racing:
  - Cheat River Race 2008, 2010-2023
  - Ohiopyle, PA, Over-the-Falls Race, 2007-2009, 2012, and 2015, [www.fallsrace.com](http://www.fallsrace.com);
  - Potomac Downriver Race 2009, 2010, 2015, 2020, 2022.
  - Potomac Little Falls Race, 2016.
- Service:
  - Chair, 2010 USA Canoe Kayak National Slalom Championships;
  - Secretary of Potomac Whitewater Racing Center, <http://bce-racing.com/blog/>.