

**NOT TOO COSTLY, AFTER ALL:
AN EXAMINATION OF THE INFLATED COST-
ESTIMATES OF HEALTH, SAFETY AND
ENVIRONMENTAL PROTECTIONS**

BIBLIOGRAPHY

3M, Annual Report, 2000.

American Cyanamid, Annual Report, 1978.

Amerisurfers, "Physics 301 - Energy and the Environment, Summer 1998,
<http://energy.fullerton.edu/amerisurfers-case3.htm>, downloaded September 7, 2001.

Arthur D. Little, Inc., Economic Impact of Environmental Regulations on the United States Copper Industry, Summary Submitted to United States Environmental Protection Agency, Contract No. 68-01-2842, January 1978.

Arthur D. Little, Inc., Economic Impact Study of the Pollution Abatement Equipment Industry, Prepared for Environmental Protection Agency, Distributed By National Technical Information Service, U.S. Department of Commerce, PB-225 841, October 1972.

Arthur D. Little, Inc., Polyvinyl Chloride, The U.S. Industry: An Impact Analysis, Arthur D. Little, Inc., Boston, August 1974.

Ashford, Nicholas A., "Understanding Technological Responses of Industrial Firms to Environmental Problems: Implications for Government Policy," Environmental Strategies for Industry, 1993.

Association of International Automobile Manufacturers, Inc., "Submitted Statement of the Association of International Automobile Manufacturers, Inc. to the Subcommittee on Technology, U.S. House of Representatives Regarding the Fastener Quality Act," October 6, 1998.

Automotive Recyclers Association, "General Automotive Recycling Statistics," http://www.autorecyc.org/docs/about/recycle_statistics.htm, downloaded August 11, 2001.

Automotive Recyclers Association, "Stormwater Best Management Practices," <http://www.autorecyc.org/docs/govt/stormwater.htm>, downloaded August 11, 2001.

Baram, Michael S., Regulation of Health, Safety and Environmental Quality and the Use of Cost-Benefit Analysis, Final Report to the Administrative Conference of the United States, March 1, 1979.

Barry, John, "Environmentalists, Industry Face Off Over EPA Limits On Smog, Soot," The Planet, Volume 4, Number 2, March 1997, <http://www.sierraclub.org/planet/199703/cleanair.asp>.

Barry, John, "Environmentalists, Industry Face Off Over EPA Limits On Smog, Soot," The Planet, Volume 4, Number 2, March 1997, <http://www.sierraclub.org/planet/199703/cleanair.asp>.

Bishamon, "Safety Smart, Productivity Wise." Advertisement, Material Handling Management, "July 2001.

Bolle, Mary Jane, Cost-Benefit Studies for OSHA Standards: Use and Misuse, Congressional Research Service, Library of Congress, 77-56E, August 22, 1977.

Booz, Allen & Hamilton Inc., Preliminary Estimates of Direct Compliance Costs and Other Economic Effects of OSHA's Generic Carcinogen Proposal on Substance Producing and Using Industries, Prepared for American Industrial Health Council, February 27, 1978.

Bresnahan, Timothy and Yao, Dennis, "The Nonpecuniary Costs of Automobile Emissions Standards," Rand Journal of Economics, abstract, Vol. 16, No. 4, Winter 1985.

Burtraw, Dallas, Krupnick, Alan, Mansur, Erin, Austin, David, and Farrell, Deirdre, The Costs and Benefits of Reducing Acid Rain, Discussion Paper 97-31-REV, Resources for the Future, Washington, DC, September 1997.

Centaur Associates Inc., "Technical and Economic Analysis of Regulating Occupational Exposure to Cotton Dust," Part I, Report prepared for OSHA, January 1983.

Center for Policy Alternatives, Massachusetts Institute of Technology, "Evaluating Chemical Regulations: Trade-Off Analysis and Impact Assessment for Environmental Decision-Making: A Case Study of Chlorinated Biphenyls," CPA-76-3/b, April 30, 1976.

Clean Air Trust, "Clean Air Act Costs: Predictions vs. Reality," Press Release, 1999, <http://www.cleanairtrust.org/costpref.html>, downloaded December 3, 2001.

Corn, Morton, "Cotton Dust: A Regulator's View," Studies in the Regulation of Economic Activity: The Scientific Basis of Health and Safety Regulation, The Brookings Institution, Washington, DC, 1981.

Cristensen, Wayne C. and Manuele, Fred A., National Safety Council, Institute for Safety Through Design, "Safety Through Design: A Brief Synopsis," <http://www.nsc.org/issues/isd/isdynop.htm>, downloaded August 11, 2001.

Crutchfield, Stephen, Buzby, Jean, Roberts, Tanya, and Ollinger, Michael, "Assessing the Costs and Benefits of Pathogen Reduction, Food Review, Volume 22, Issue 2, May-August, 1999.

Crutchfield, Stephen, Buzby, Jean, Roberts, Tanya, Ollinger, Michael, and Lin, C. T. Jordan, "An Economic Assessment of Food Safety Regulations: The New Approach to Meat and Poultry Inspection," Agricultural Economic Report No. 755, Economic Research Service, U.S. Department of Agriculture, July 1997.

CSI Engineering, <http://www.csiengineering.com>, downloaded August 11, 2001.

D.H.A. Pollution Control, "Golf Course Irrigation," <http://www.dha-pollution.com.uk/private/text/gci.htm>, downloaded August 11, 2001.

Daniels, Mitchell E., Memorandum for the Heads and Acting Heads of Executive Departments and Agencies, in 2000 Report to Congress on the Costs and Benefits of Federal Regulation, January 26, 2001.

"Designing a Better Way," Advertisement, Pollution Equipment News, August 2001.

Dirks-Mason, Susan and Ruttenberg, Ruth, "The Effects of the OSHA Vinyl Chloride Industry," unpublished paper, OSHA Policy Office, 1979.

Dowie, Mark, "Pinto Madness," Mother Jones, September/October 1977.

Driesen, David, M., "The Societal Cost of Environmental Regulation: Beyond Administrative Cost-Benefit Analysis," Ecology Law Quarterly, 24 Ecology L.Q. 545, 1997.

Duma, S., Crandall, J., Rudd, R., and Pilkey, W., "A Discussion of the Automotive Airbag System and the Changes in Its Federal Regulation," <http://auto-safety.mech.virginia.edu/DatabaseConnection/presentations/Duma-Safety97.pdf> 1997.

DuPont, Annual Report, 2000.

Eastern Research Group, Inc, for U.S. Food and Drug Administration, Office of Planning and Evaluation, "Cost Analysis of Regulatory Options to Reduce the Risk of an Outbreak of Transmissible Spongiform Encephalopathies (TSEs) in the United States," Final Report, December 31, 1996.

Eastern Research Group, Inc, Cost Analysis of Regulatory Options to Reduce the Risk of an Outbreak of Transmissible Spongiform Encephalopathies (TSEs) in the United States, Addendum to the Final Report, for U.S. Food and Drug Administration, Contract No. 223-94-8031, April 30, 1997.

Environmental Compliance Assistance Center, "General Pollution Prevention Information," <http://www.hazmat.frcc.ccco.es.edu/pollprev.htm>, downloaded September 7, 2001.

eSafety.com, "New Federal Safety Standard for Bunk Beds, [wysiwyg://10http://www.esafety.com/esafety_cfmfiles/esafety.cfm/124](http://www.esafety.com/esafety_cfmfiles/esafety.cfm/124), downloaded September 7, 2001.

Ford Motor Co., Annual Report, 2000.

General Motors, Annual Report, 2000.

Geoprobe Systems, "Designing a Better Way," advertisement, Pollution Equipment News, August 2001.

Gerrard, Michael, "The Economic Benefits of a Clean Environment." OpEd, Washington Post, July 20, 1976.

Gerstenfeld, Arthur, "Government Regulation Effects on the Direction of Innovation: A Focus on Performance Standards," IEE Transactions on Engineering Management, Vol. EM-24, No. 3, August 1977.

Goodstein, Eban and Hodges, Hart, "Polluted Data: Overestimating Environmental Costs," The American Prospect, No. 35, November-December 1997.

Goodstein, Eban, The Trade-Off Myth: Fact and Fiction About Jobs and the Environment, Island Press, 1999.

Gray, Wayne B., "The Cost of Regulation: OSHA, EPA and the Productivity Slowdown," The American Economic Review, Vol. 77, No. 5, December 1987.

Hahn, Robert and Hird, John, "The Costs and Benefits of Regulation: Review and Synthesis," Yale Journal on Regulation, Vol. 8, 1990.

Harrington, Winston, Morgenstern, Richard, and Nelson, Peter, "On the Accuracy of Regulatory Cost Estimates," Discussion Paper 99-18, Resources for the Future, Washington, DC, January 1999.

Heiden Associates, "Recall Effectiveness Research: A Review and Summary of the Literature on Consumer Motivation and Behavior," prepared for the U.S. Consumer Product Safety Commission, CPSC Order CPSC-F-02-1391, Contract GS23F9780H, July 2003, 150 pages.

Heinzerling, Lisa, "Regulatory Costs of Mythic Proportions," The Yale Law Journal, Vol. 107, 1998.

Hodges, Hart, "Falling Prices: Cost of Complying with Environmental Regulations Almost Always Less Than Advertised," Briefing Paper, Economic Policy Institute, #199711, 1997.

Hopkins, Thomas, "The Costs of Federal Regulation," Journal of Regulation and Social Costs, March 1992.

Hubbard, Robert, Ex-Vice President, Cargill, Statement at OSHA's Public Meeting on Review of the Grain Handling Standard, June 12, 1984.

ICF, Inc. and MIT Center for Policy Alternatives, Regulatory Analysis Methods: A Review of Past Health-Related Efforts, Draft, July 1979.

Illinois Institute of Technology, National Center for Food Safety and Technology (NCFST), "NCFST History Location and Physical Plant," <http://www.itt.edu/~ncfs/ressafe.html>, downloaded September 3, 2001.

Injury Lawyer Network, <http://www.injury-lawyer-network.com>, downloaded September 7, 2001.

Institute of Clean Air Companies (ICAC), <http://www.icac.com/welcome.html>, downloaded August 11, 2001.

Insurance Institute for Highway Safety, "Impressive Crash Test Performance for Vehicles With Side Airbags That Protect Occupants' Heads," News Release, December 14, 2000.

James, Harvey S., Jr., Estimating OSHA Compliance Costs, Washington University, Center for the Study of American Business, Policy Study Number 135, October 1996.

Jensen-Korte, Uta, "Review of the EU Chemicals Policy," Global Chemical Regulations Conference, March 12-15, 2001.

Jones, Ray, E. I. DuPont, Presentation at OSHA's public meeting on review of the Control of Hazardous Energy Sources (Lockout/Tagout) Standard, June 30, 1997.

Joskow, Paul and Rose, Nancy, "The Effects of Technological Change, Experience, and Environmental Regulation on the Construction Cost of Coal-Burning Generating Units," Rand Journal of Economics, abstract, Vol. 16, No. 1, Spring 1985.

Kelman, Steven, "Cost-Benefit Analysis - An Ethical Critique," Regulation, January/February 1981.

Kelsan Friction Innovators and Portec Rail Products, Inc., "Got and Earful of Noise? Noise Abatement That's ... Immediate, Proven!" Advertisement, Railway Age, August 2001.

Kennecott, Annual Report, 1978.

Kuchler, Fred and Golan, Elise, "Assigning Values to Life: Comparing Methods for Valuing Health Risks," Agricultural Economics Report No. 784, U.S. Department of Agriculture, December 1999.

Laitner, Skip, Goldberg, Marshall, Sheehan, Michael, and Baldwin, Marc, "Environment and Jobs: The Employment Impact of Federal Environment Investments," National Commission for Employment Policy, Research Report No. 95-02, April 1995.

Lanoie, Paul and Trottier, Louis, "Costs and Benefits of Preventing Workplace Accidents: Going from a Mechanical to a Manual Handling System," Journal of Safety Research Vol. 29, No. 2, Summer 1998.

Levin, Richard, "Allocation in Surface Freight Transportation: Does Rate Regulation Matter?" Rand Journal of Economics, abstract, Volume 9, No. 1, Spring 1978.

Maciariello, Joseph, Dynamic Benefit-Cost Analysis, Lexington Books, Toronto and London, 1975.

Magat, Wesley and Moore, Michael, "Consumer Product Safety Regulation in the United States and the United Kingdom: The Case of Bicycles," Rand Journal of Economics, abstract, Volume 27, No. 1, Spring 1996.

Majchrowicz, Alex, "Innovative Technologies Could Improve Food Safety," Food Review, Volume 22, Issue 2, May-August 1999.

Maloney, M. T. and McCormick, R. E., "A Positive Theory of Environmental Quality Regulation," Journal of Law and Economics, Vol. XXV, April 1982.

Manitoba Government, Department of Environment and Workplace Safety and Health, Potential Economic Benefits and Market Opportunities Resulting From the Manitoba Workplace Health Regulation, submitted to the Province of Manitoba and the Manitoba Federation of Labour, February 1985.

Martin, P. G., Crandall, J. R., Pilkey, W. D., and Miller, T. R., "Passenger Car Drivers: Annual Injury Incidence and Costs Projected to 2005," 1997, <http://auto-safety.mech.virginia.edu/DatabaseConnection/Papers/PeterAAAM97.pdf>, downloaded August 11, 2001.

McGarity, Thomas and Ruttenberg, Ruth, "Counting the Cost of Health, Safety, and Environmental Regulation," Texas Law Review, Vol. 80, No. 7, June 2002.

McGarity, Thomas and Shapiro, Sidney, Workers At Risk: The Failed Promise of the Occupational Safety and Health Administration, Praeger, Connecticut and London, 1993.

McGarity, Thomas, "A Cost-Benefit State," Administrative Law Review, Vol. 50, No. 1, Winter 1998.

McGarity, Thomas, "Radical Technology-Forcing in Environmental Regulation," Loyola of Los Angeles Law Review, Spring 1994.

Mendeloff, John, The Dilemma of Toxic Substance Regulation, MIT Press, Cambridge, Massachusetts, 1988.

Mercer Management Consulting, "Preliminary Regulatory Impact Analysis for Vessel Response Plans," for the U.S. Coast Guard, April 21, 1992.

Minnesota Pollution Control Agency, Policy and Planning Division, Remediation and P2/S Programs, "The Link Between Remediation, Pollution Prevention and Sustainable Activities," <http://www.pca.state.mn.us/programs/p2-s/remediation/index.html>, downloaded August 11, 2001.

Minnesota Pollution Control Agency, Policy and Planning Division, Remediation and P2/S Programs, Pollution Prevention & Sustainable Activities at Remediation Sites, p-p2s-01, April 2001.

Monsanto, Annual Report, 2000.

Morgenstern, Richard D., Economic Analyses at EPA: Assessing Regulatory Impact, Resources for the Future, Washington, DC, 1997.

Morrall, John F. III, "Current Methodologies for Comparing the Costs of Controls with the Benefits: Examples from the Council on Wage and Price Stability's Analyses of OSHA Standards," U.S. Council on Wage and Price Stability, August 22, 1979.

National Commission for Employment Policy, "Environment and Jobs: The Employment Impact of Federal Environmental Investments," 1995.

National Commission for Employment Policy, "The Employment Impact of Federal Environmental Investments," 1995.

National Food Safety Information Network, "The Government Agencies," <http://www.foodsafety.gov/~fsg/fsggov.htm>, downloaded September 3, 2001.

National Hazmat Program, Assessing the Full Costs of New Remediation Technologies: Preliminary Guidelines for Identifying Occupational Safety and Health Costs for Environmental Remediation Technologies, for the U.S. Department of Energy, 2001.

National Occupational Safety and Health Commission, Australia, "Use of Glovebags," <http://www.nohsc.gov.au/OHSInformation/NOHSCPublications/fulltext/docs/h5/261.htm>, downloaded November 2, 2001.

National Paint and Coatings Association, "150 NPCA Pollution Prevention Ideas," http://www.paint.org/ind_issue/pollu.htm, downloaded September 7, 2001.

National Safety Council, Institute for Safety Through Design, "About the Institute -- A Benchmark for Change in Safety," <http://www.nsc.org/istd/aboutus.htm>, downloaded August 11, 2001.

National Safety Council, Institute for Safety Through Design, "Engineering Criteria 2000: Engineering Education," <http://www.nsc.org/issues/isd/isdeduc.htm>, downloaded August 11, 2001.

NetCompliance, "NHTSA Issues Concern About Mobile Construction Equipment Using Public Roads, Net Compliance, Inc. Reveals," <http://www.netcompliance.com/pages/construction.htm>, May 10, 2001.

North American Insulation Manufacturers Association (NAIMA), "Fiber Glass & Slag Wool Insulations – Materials for a Sustainable Planet, Insulation Facts #45," <http://www.naima.org/docs/N012.html>, downloaded August 11, 2001.

North American Insulation Manufacturers Association (NAIMA), "Insulation and the Environment," <http://www.naima.org/enviroen.shtml>, downloaded August 11, 2001.

Ohio Environmental Protection Agency, Office of Pollution Prevention, "Waste: What is It Really Costing You?" Number 72, August 1999.

Palmer, Karen, Oates, Wallace E., and Portney, Paul R., "Tightening Environmental Standards: The Benefit-Cost of the No-Cost Paradigm?" Journal of Economic Perspectives, Volume 9, Number 4, Fall 1995.

Pauli Systems, "Dry Media Depainting and EPA, OSHA Compliance," <http://www.paulisystems.com/page/epa.htm>, downloaded September 7, 2001.

Petroleum Technology Transfer Council, "Higher Gas Prices Mean Greater Cost Savings from Reducing Methane Emissions," PTTC Network News, 1st Quarter 2001.

Pinkham, Jim, "Cotton Dust Standard Endures 10 Years," Occupational Health and Safety, May 1988.

Pollution Control Systems, Inc., <http://www.pollutioncontrolsystem.com>, downloaded August 11, 2001.

Porter, Michael E. and van der Linde, Claas, "Toward a New Conception of the Environment-Competitiveness Relationship," Journal of Economic Perspectives, Vol. 9, No. 4, Fall 1995.

Porter, Michael E., "America's Green Strategy," Scientific American, April 1991.

Portney, Paul, Ed., Current Issues in U.S. Environmental Policy, Resources for the Future, Washington, DC, 1978.

Public Citizen, "Tufts Drug Study Sample is Skewed; True Figure of R&D Costs Likely is 75 Percent Lower," press release, December 4, 2001.

"PVC Rolls Out of Jeopardy, Into Jubilation," Chemical Week, September 15, 1976.

Raafat, Hani and Simpson, Perry, National Safety Council, Institute for Safety Through Design, "Integrating Safety During the Machine Design Stage," <http://www.nsc.org/issues/isd/isdmach.htm>, downloaded August 11, 2001.

Research Triangle Institute (RTI), Cotton Dust: Technological Feasibility Assessment and Final Inflationary Impact Statement, Part I, Report prepared for OSHA, 1976.

Rest, Kathleen and Ashford, Nicholas, "Regulation and Technological Options: The Case of Occupational Exposure to Formaldehyde," Harvard Journal of Law and Technology, Volume 1, Spring Issue, 1988.

Robinson, James C., "The Impact of Environmental and Occupational Health Regulation on Productivity Growth in U.S. Manufacturing," The Yale Journal on Regulation, Vol. 12, No. 387, 1995.

Ross, Kurt, "New Glovebag Regulations Allow Safer, Cheaper Asbestos Removal," Occupational Health and Safety, September 1996.

Ruth Ruttenberg & Associates, Inc., "Regulatory Review of OSHA's Cotton Dust Standard [29 CFR 1910.1043] Pursuant to Section 610 of the Regulatory Flexibility Act and Section 5 of Executive Order 12866," prepared for the Office of Program Evaluation, Occupational Safety and Health Administration, September 2000.

Ruth Ruttenberg & Associates, Inc., "Regulatory Review of OSHA's Grain Handling Standard [29 CFR 1910.272] Pursuant to Section 610 of the Regulatory Flexibility Act and Section 5 of Executive Order 12866," Draft, prepared for the Office of Program Evaluation, Occupational Safety and Health Administration, August 2000.

Ruth Ruttenberg & Associates, Inc., "Summary of Data and Analysis for Section 610 and EO12866 Review of OSHA's Control of Hazardous Energy Sources (Lockout/Tagout) Standard," prepared for the Office of Regulatory Analysis, Occupational Safety and Health Administration, April 1998.

Ruth Ruttenberg & Associates, Inc., "Summary of Data and Analysis for Section 610 and EO 12866 Review of OSHA's Ethylene Oxide Standard," prepared for the Office of Regulatory Analysis, Occupational Safety and Health Administration, April 1998.

Ruth Ruttenberg, "New Definitions and Techniques for Assessing Costs and Benefits," Labor Studies Journal, Spring 1981.

Ruttenberg, Ruth, "Can Protecting Human Health and the Environment Be Justified on Cost-Benefit Grounds?" Preventive Strategies for Living in a Chemical World, Annals of the New York Academy of Sciences, Volume 837, December 26, 1997.

Ruttenberg, Ruth, "Compliance With the OSHA Grain Handling Rule: Safety Measures Save Life and Dollars," for U.S. Office of Technology Assessment, Study of OSHA's Choice of Control Technology and Estimation of Economic Impacts, Contract K3-0841.0, June 1994.

Ruttenberg, Ruth, "Is OMB Interfering With Worker Health and Safety Protection?" Statement Presented March 19, 1992 to the U.S. Congress, Senate Committee on Governmental Affairs Hearings."

Ruttenberg, Ruth, "Regulation is the Mother of Invention," Working Papers for a New Society, May/June 1981.

Ruttenberg, Ruth, "Statement of Dr. Ruth Ruttenberg Before the Subcommittee on Regulation and Paperwork, Committee on Small Business and Subcommittee on Oversight and Investigations, Committee on Economic and Educational Opportunities, U.S. House of Representatives, Joint Hearing on the Impact Regulations on Business," February 2, 1995.

Ruttenberg, Ruth, "Statement of Ruth Ruttenberg on Behalf of the AFL-CIO Before the Occupational Safety and Health Administration's Public Hearings on Proposed Noise Standards," Washington, DC, July 1975.

Ruttenberg, Ruth, "Statement of Ruth Ruttenberg on Behalf of the AFL-CIO, 'Occupational Safety and Health Administration Hearings on the Proposed Regulation for the Identification, Classification and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk,'" July 10, 1978.

Ruttenberg, Ruth, "Testimony of Dr. Ruth Ruttenberg Before the Subcommittee on Investigation and Oversight of the House Committee on Science and Technology," September 22, 1982.

Ruttenberg, Ruth, "Testimony of Dr. Ruth Ruttenberg, On Behalf of the Building and Construction Trades Department, AFL-CIO, Before the Occupational Safety and Health Administration, Public Hearings on the Concrete and Masonry Construction Safety Standard," June 17, 1986.

Ruttenberg, Ruth, "The Gold in Rules," Environmental Action, October 1981.

Ruttenberg, Ruth, "Why Social Regulatory Policy Requires New Definitions and Techniques for Assessing Costs and for Assessing Benefits: The Case of Occupational Safety and Health," Labor Studies Journal, Vol. 6, No. 1, Spring 1981.

Ruttenberg, Ruth, Compliance With the OSHA Cotton Dust Rule - The Role of Productivity Improving Technology, prepared for the U.S. Congress, Office of Technology Assessment, March 1983.

Ruttenberg, Ruth, The Incorporation of Prospective Technological Changes into Regulatory Analysis Which is Used in the Planning of Occupational Safety and Health Regulations, Ph.D. Dissertation, University of Pennsylvania, 1981.

Ruttenberg, Ruth, Weinstock, Deborah, and Santamaria, Lina, Labor Market Study of Hazardous Waste Workers and Associated Emergency Responders, for the Environmental Protection Agency and the National Institute of Environmental Health Sciences, November 1994, p. 4.

School Transportation.com, "Final Rule: FMVSS 201 Head Impact Protection," <http://www.stnonline.com/stn/schoolbuslibrary/federalregs/201.htm>, downloaded September 7, 2001.

Shapiro, Sidney A. and Rabinowitz, Randy S., "Punishment Versus Cooperation in Regulatory Enforcement: A Case Study of OSHA," Administrative Law Review, Volume 49, Number 4, Fall 1997.

Shapiro, Sidney A. and Rabinowitz, Randy S., "Voluntary Regulatory Compliance in Theory and Practice: The Case of OSHA," Administrative Law Review, Volume 52, Number 1, Winter 2000.

Siegel, Stuart, Evaluating the Cost Effectiveness of the Title IV Acid Rain Provisions of the 1990 Clean Air Act Amendments, doctoral thesis, Carnegie Mellon University, abstract, <http://www.epp.cmu.edu/news/page6.html>, downloaded September 6, 2001.

Smart, Bruce, ed., Beyond Compliance: A New Industry View of the Environment, World Resources Institute, April 1992.

Smith, L. E., Greene, M. A., and Singh, H. A., U.S. Consumer Product Safety Commission, "Study of the effectiveness of the US safety standard for child resistant cigarette lighters," *Injury Prevention* 2002; 8:192-196, October 2002.

Stanford University, Department of Environmental Health and Safety, "Ozone Depleting Substitutes Phase Out Plan," March 1996.

State and Territorial Air Pollution Program Administrators (STAPPA), "About Us," <http://www.4cleanair.org/about.html>, downloaded August 11, 2001.

Stauffer, Annual Report, 1978.

Stone, Robert F., A Retrospective Analysis of the Economic Impact on Foundries of OSHA's 1987 Formaldehyde Standard, prepared for the U.S. Congress, Office of Technology Assessment, OTA Contract K3-1036 and M3-0566, August 1994.

Stone, Robert F., An Evaluation of OSHA's Resources for Regulatory Analysis, prepared for the U.S. Congress, Office of Technology Assessment, M3-0711, March 1995.

Stone, Robert F., Three Case Studies of OSHA's Regulatory Impact Analysis in Support of Recent Rulemaking, prepared for the U.S. Congress, Office of Technology Assessment, K3-0306, February 1994.

Straube, Michele and Ruttenberg, Ruth, "Comments on Regulatory Impact Analyses for Vessel Response Plans and Section 5005 Requirements," prepared for Prince William Sound Citizens Advisory Council (Alaska), in response to Coast Guard Regulatory Analyses, 1992.

Sunstein, Cass, "The Arithmetic of Arsenic," John M. Olin Law & Economics Working Paper No. 135 (2D Series) and Joint Center, AEI-Brookings Joint Center for Regulatory Studies, Working Paper 01-10, <http://www.law.uchicago.edu/Lawecon/index.html>, downloaded November 7, 2001.

Taylor, Michael R. and Hoffmann, Sandra A., "Redesigning Food Safety," Resources, Resources for the Future, Issue 144, Summer 2001.

The Air Bag Center, <http://www.airbagcenter.com/>, downloaded September 3, 2001.

U.S. Congress, Office of Technology Assessment, Gauging Control Technology and Regulatory Impacts in Occupational Safety and Health: An Appraisal of OSHA's Analytic Approach, OTA-ENV-635, Washington, DC: U.S. Government Printing Office, GPO stock # 052-003-01445-9, September 1995.

U.S. Consumer Product Safety Commission, "Compliance Program Spurs Product Safety," <http://www.cpsc.gov/cpscpub/pubs/success/sec15.html>, downloaded August 1, 2001.

U.S. Consumer Product Safety Commission, "Consumers To Benefit From Safety-Related Economic Trends," June 6, 1977, <http://www.cpsc.gov/cpscpub/pubs/prerel/prhtml177/77056.html>, downloaded August 11, 2001.

U.S. Consumer Product Safety Commission, "Corporations Provide Preliminary Data on Hair Dryers with Asbestos," April 6, 1979.

U.S. Consumer Product Safety Commission, "CPSC Accepts Corrective Actions From Major Hair Dryer Companies," May 21, 1979.

U.S. Consumer Product Safety Commission, "CPSC and Industry: Saving Lives Cost-Effectively Through Cooperation, Child-resistant Cigarette Lighters," <http://www.cpsc.gov/cpscpub/pubs/success/lighters.html>, downloaded August 11, 2001.

U.S. Consumer Product Safety Commission, "CPSC Lead-in-Paint Activities Reduce Consumer Exposure to Lead," <http://www.cpsc.gov/cpscpub/pubs/success/lead.html>, downloaded August 1, 2001.

U.S. Consumer Product Safety Commission, "CPSC Mandatory Bicycles Safety Standards Reduce Injuries: Continued Work with Industry to Make Bike Riding Safer," <http://www.cpsc.gov/cpscpub/pubs/success/bikes.html>, downloaded August 1, 2001.

U.S. Consumer Product Safety Commission, "CPSC Staff Recommends Safety Standard for Flammable Upholstered Furniture," November 20, 1978.

U.S. Consumer Product Safety Commission, "Economic analysis estimates related to Petition HP 95-1," Memorandum from Ronald L. Medford, Assistant Executive Director, Office of Hazard Identification and Reduction and Elizabeth W. Leland, Economist, Directorate for Economic Analysis, January 7, 1997.

U.S. Consumer Product Safety Commission, "Economic Considerations - GFCIs," Memorandum from Terrace R. Karels, Directorate for Economic Analysis, March 10, 2003.

U.S. Consumer Product Safety Commission, "Regulated Products," <http://www.cpsc.gov/businfo/reg.html>, downloaded August 11, 2001.

U.S. Consumer Product Safety Commission, Directorate for Engineering Sciences, "Final Report on Electric Clothes Dryers and Lint Ignition Characteristics," May 2003.

U.S. Consumer Product Safety Commission, "Metal-Cored Candelwicks Containing Lead and Candles with Such Wicks," Final Rule, in Federal Register: 16 CFR Part 1500, Vol. 68, No. 75, April 18, 2003.

U.S. Consumer Product Safety Commission, "Safety Standard for Multi-Purpose Lighters," Final Rule, in Federal Register: 16 CFR Part 1212, Vol. 64, No. 245, December 22, 1999.

U.S. Consumer Product Safety Commission, "Flammable Fabrics Act: Children's Sleepwear (Sizes 0-6x, 7-14) Flammability Standards," Final Amendments, in Federal Register: 16 CFR Part 1615 and 1616, Vol. 61, No. 175, September 9, 1996.

U.S. Consumer Product Safety Commission, Memorandum from Terrace R. Karels, Directorate for Economic Analysis, "Economic Considerations - AFCI Replacements," March 10, 2003.

U.S. Consumer Product Safety Commission, Office of Information and Public Affairs, "Commission Initiates Formal Rule for Assessing Costs & Benefits of Its Regulations," March 12, 1981.

U.S. Department of Agriculture, Food Safety and Inspection Service, "FSIS and FDA Working Together to Make Eggs Safer," April 21, 2000.

U.S. Department of Agriculture, Food Safety and Inspection Service, "Protecting the Public From Foodborne Illness: The Food Safety and Inspection Service," April 2001.

U.S. Department of Agriculture, Food Safety and Inspection Service, "Today's Technology Helps Meat and Poultry Inspectors Improve Job Performance," November 1, 2000.

U.S. Department of Energy, Energy Information Administration, The Effects of Title IV of the Clean Air Act Amendments of 1990 on Electric Utilities: An Update, Executive Summary, March 1997.

U.S. Department of Energy, Lawrence Livermore National Laboratory, "Environmental Risk Reduction," <http://222.llnl.gov/str/FFEnviro.html>, downloaded September 6, 2001.

U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Food Safety Office, Division of Bacterial and Mycotic Diseases, "Partners in Food Safety," <http://www.cdc.gov/foodsafety/partners.htm>, downloaded September 3, 2001.

U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, "Proceedings: New Technology for Coal Mine Roof Support," Information Circular (IC) 9453, Technology News – Milestone in Mining Safety and Health Technology, No. 493, August 2001.

U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, "Proceedings of the Second International Workshop on Coal Pillar Mechanics and Design," Information Circular (IC) 9448, Technology News – Milestone in Mining Safety and Health Technology, No. 492, August 2001.

U.S. Department of Health and Human Services, Food and Drug Administration, Office of Planning and Evaluation, "Cost Analysis of Regulatory Options to Reduce the Risk of an Outbreak of Transmissible Spongiform Encephalopathies (TSEs) in the United States," Addendum to the Final Report, April 30, 1997.

U.S. Department of Health and Human Services, Food and Drug Administration, "Current Good Manufacturing Practices (CGMP's), Analysis of Economic Impact," Presentation at April 29, 2003 and May 6, 2003 Public Meetings.

U.S. Department of Justice, Americans with Disabilities Act of 1990, 101st Congress, 2nd Session, January 23, 1990.

U.S. Department of Labor, Occupational Safety and Health Administration, Final Report: Economic Impact Assessment for Acrylonitrile, February 21, 1978.

U.S. Department of Labor, Occupational Safety and Health Administration, Final Economic and Regulatory Flexibility Analysis for OSHA's Standard for Occupational Exposure to Methylene Chloride, January 7, 1996.

U.S. Department of Labor, Occupational Safety and Health Administration, Preliminary Regulatory Impact and Regulatory Flexibility Analysis of the 1, 3-Butadiene Standard, June 1989.

U.S. Department of Labor, Occupational Safety and Health Administration, Regulations (Standards - 29 CFR), "Methylene Chloride," 1910.1052, http://www.osha-slc.gov/OshStd_data/1910_1052.html.

U.S. Department of Labor, Occupational Safety and Health Administration, Regulatory Impact and Regulatory Flexibility Analysis of the Occupational Safety and Health Standard for Hazardous Waste Operations and Emergency Response (29 CFR Part 1910), December 14, 1988.

U.S. Department of Labor, Occupational Safety and Health Administration, Regulatory Review of OSHA's Cotton Dust Standard, September 2000.

U.S. Department of Labor, Occupational Safety and Health Administration, "Technical Links: Formaldehyde," <http://www.osha-slc.gov/SLTC/formaldehyde/index.html>, downloaded November 3, 2001.

U.S. Department of Transportation, National Highway Traffic Safety Administration, "Evaluation Program Plan: Summaries of Completed Evaluation Reports," 1998, <http://www.nhtsa.dot.gov/cars/rules/regrev/evaluate/EP/Completed.htm>, downloaded August 1, 2001.

U.S. Department of Transportation, National Highway Traffic Safety Administration, Final Rule: FMVSS 201, Head Impact Protection in School Transportation News on the Web, <http://www.stnonline.com/stn/schoolbuslibrary/federalregs/201.htm>, downloaded September 7, 2001.

U.S. Department of Transportation, National Highway Traffic Safety Administration, Office of Regulatory Analysis and Evaluation Plans and Policy, Final Economic Assessment, VMVSS No. 213, FMVSS No. 225, Child Restraint Systems, Child Restraint Anchorage Systems, February 1999.

U.S. Department of Transportation, National Highway Traffic Safety Administration, Office of Regulatory Analysis & Evaluation Plans and Policy, "Preliminary Economic Assessment and Regulatory Flexibility Analysis: FMVSS No. 202, Head Restraints for Passenger Vehicles," December 2000.

U.S. Department of Transportation, National Highway Traffic Safety Administration, Office of Regulatory Analysis and Evaluation Plans and Policy, "Preliminary Economic Assessment: SNPRM, FMVSS No. 208, Advanced Air Bags," October 1999, Introduction.

U.S. Department of Transportation, National Highway Traffic Safety Administration, Office of Regulatory Analysis and Evaluation Plans and Policy, "Final Economic Assessment: FMVSS No. 208, Advanced Air Bags," May 2000.

U.S. Department of Transportation, National Highway Traffic Safety Administration, Office of Regulatory Analysis and Evaluation Plans and Policy, "Tire Pressure Monitoring System, FMVSS No. 138," Chapter VI, July 2001.

U.S. Department of Transportation, Office of Industry Policy, "Guidance for Regulatory Evaluations: A Handbook for DOT Benefit-Cost Analysis," April 1984.

U.S. Environmental Protection Agency, Environmental Economics Report Inventory: The Benefits and Costs of the Clean Air Act 1990 to 2010: EPA Report to Congress, <http://yosemite1.epa.gov/EE/epa/ee.../490de3d62654580c8525683a007ace54?OpenDocument>, downloaded August 11, 2001.

U.S. Environmental Protection Agency, Office of Emergency and Remedial Response, Office of Program Management, Policy and Contracts Assessment Staff, Economic Impact of the Superfund Program: Fiscal Years 1981-1992, Draft, July 1994.

U.S. Environmental Protection Agency, Office of Emergency and Remedial Response, Office of Program Management, Policy and Contrasts Assessment Staff, Technical Report - Economic Impact of the Superfund Program: 1981-1992, Draft, June 16, 1994.

U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics, <http://www.epa.gov/opptintr/pcb/> - BACKGROUND INFORMATION, downloaded December 4, 2001.

U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics, <http://www.epa.gov/opptintr/pcb/> - Health Effects Studies, downloaded December 4, 2001.

U.S. General Accounting Office, "Environmental Protection: Wider Use of Advanced Technologies Can Improve Emissions Monitoring," abstract, GAO-01-313, June 22, 2001.

U.S. General Accounting Office, Air Pollution -- Information Contained in EPA's Regulatory Impact Analyses Can Be Made Clearer, GAO/RCED-97-38, April 1997.

U.S. General Accounting Office, Environmental Protection -- Assessing the Impacts of EPA's Regulations Through Retrospective Studies, GAO/RCED-99-250, September 1999.

U.S. General Accounting Office, Food and Drug Administration: Over-the-Counter Human Drugs; Labeling Requirements, memo and analysis, GAO/OCG-99-36, April 1, 1999.

U.S. General Accounting Office, Food Safety: Federal Oversight of Shellfish Safety Needs Improvement, GAO-01-702, July 9, 2001.

U.S. General Accounting Office, International Environment -- Literature Effectiveness of International Environmental Agreements, GAO/RCED-99-148, May 1999.

U.S. General Accounting Office, Regulatory Burden -- Measurement Challenges and Concerns Raised by Selected Companies, GAO/GGD-97-2, November 1996.

U.S. General Accounting Office, Report to the Chairman, Committee on Governmental Affairs, U.S. Senate, Risk-Risk Analysis -- OMB's Review of a Proposed OSHA Rule, PEMD-92-33, July 1992.

U.S. General Accounting Office, Report to the Chairman, Subcommittee on Water and Power Resources, Committee on Resources, House of Representatives, Air Pollution -- Estimated Benefits and Costs of the Navajo Generating Station's Emissions Limit, GAO/RCED-98-28, January 1998.

U.S. General Accounting Office, Results Act -- Observations on the U.S. Department of Agriculture's Fiscal Year 2000 Performance Plan, GAO/RCED-99-187, June 1999.

U.S. General Accounting Office, Testimony Before the Subcommittee on Energy and Environment Committee on Science House of Representatives, Superfund -- Use of Innovative Technologies for Site Cleanups, Statement by Lawrence J. Dyckman, Associate Director, Environmental Protection Issues, Resources, Community, and Economic Development Division, T-RCED-96-45, December 6, 1995.

U.S. General Accounting Office, Testimony Before the Subcommittee on Oversight and Investigations Committee on Commerce, House of Representatives, "Environmental Protection -- EPA's and States' Efforts to 'Reinvent' Environmental Regulation," Statement of Peter F. Guerrero, Director, Environmental Protection Issues, Resources, Community, and Economic Development Division, T-RCED-98-33, November 4, 1997.

U.S. General Accounting Office, Testimony Before the Subcommittee on Water Resources and Environment, Committee on Transportation and Infrastructure, House of Representatives, Superfund -- EPA's Use of Risk Assessments in Cleanup Decisions, Statement of Lawrence J. Dyckman, Associate Director, Environmental Protection Issues, Resources, Community, and Economic Development Division, T-RCED-95-231, June 22, 1995.

U.S. General Accounting Office, USDA's Fiscal Year 2000 Performance Plan, GAO/RCED-99-187, June 1999.

U.S. General Accounting Office, Vehicle Safety: Technologies, Challenges, and Research and Development Expenditures for Advanced Air Bags, GAO-01-596, June 2001.

U.S. Navy, Environmental Program, "Do you use two part epoxy paints?," February 1998.

U.S. Office of Management and Budget, "Economic Analysis of Federal Regulations Under Executive Order 12866," January 11, 1996.

U.S. Office of Management and Budget, 1998 Report of OMB to Congress on the Costs and Benefits of Federal Regulations, 1998.

U.S. Office of Management and Budget, 2000 Report to Congress on the Costs and Benefits of Federal Regulations, 2000.

U.S. Senate, Subcommittee on the Environment, Committee on Commerce, "Hearing to Regulate Commerce and Protect Human Health and the Environment by Requiring Testing and Necessary Use Restrictions on Certain Chemical Substances, and for Other Purposes," Part 2, Serial No. 94-24, Government Printing Office, Washington, DC, October 24, 1975.

Union Carbide, Annual Report, 1978.

United Steelworkers of America, AFL-CIO CLC, "Post-Hearing Brief of United Steelworkers of America, AFL-CIO CLC on Standard for Coke Oven Emissions," June 16, 1976.

University of Minnesota, Minnesota Technical Assistance Program, "Waste Reduction and Cost Saving Ideas for Wood Finishers," <http://www.mnta.umn.edu/PAINT/Wood-7.htm>, downloaded September 7, 2001.

Viscusi, W. Kip, "Mortality Effects of Regulatory Costs and Policy Evaluation Criteria," RAND Journal of Economics, Vol. 25, No. 1, Spring 1994.

Viscusi, W. Kip, "Cotton Dust Regulation: An OSHA Success Story?" Journal of Policy Analysis and Management, Vol. 4, No. 3, 1985.

Volpe National Transportation Systems Center, Research and Special Programs Administration, U.S. Department of Transportation, "Preliminary Regulatory Impact Analysis for the Oil Pollution Act of 1990, Section 5005, Equipment and Personnel Requirements Under Vessel Response Plans For Tank Vessels Operating in Prince William Sound," for Coast Guard, April 1992.

Webster, Neil, "Bucket Elevators: How to Operate and Maintain Them Efficiently," Oklahoma Grain Elevator Workshop Manual, 1991.

Wheelabrator Air Pollution Control Inc., <http://www.wapc.com>, downloaded August 11, 2001.

Wisconsin Department of Natural Resources, Bureau of Cooperative Environmental Assistance, "Pollution Prevention Case Study, 3D Manufacturing, Inc.: Energy Conservation and Waste Reduction through Enhanced Process Management," PUBL-CO-056, http://www.dnr.state.wi.us/org/caer/cea/casestudy/casestudies/co_056.htm, downloaded September 7, 2001.

Regulation and Competitiveness¹

Anti-regulatory arguments claim that regulation is inherently a burden that weakens the competitiveness of American businesses in the global market. Yet a plethora of scholarly studies indicates that the opposite is true: regulation not only does not hinder U.S. competitiveness but actually may increase the competitive advantage of the United States. Overall, factors such as wages and trade agreements play a much larger role than regulation in determining U.S. competitiveness. Economists have been unable to find the strong negative correlation between regulation and competitiveness. This finding may run counter to intuition, but it suggests that protecting public health, safety and the environment can have real economic advantages; the United States does not have to sacrifice public protections in order to promote U.S. competitiveness.

1. Economic indicators fail to show an environment/competitiveness tradeoff.

Economists look at several economic indicators to determine the impact of regulation on competitiveness, such as plant location, industry imports and exports, and foreign direct investment (FDI). The argument that regulation harms U.S. competitiveness is based primarily on the theory that pollution-intensive industries will move to areas with more lax environmental regulations ("pollution havens") in order to avoid the costs of compliance with more stringent environmental protections. If the pollution haven theory holds, then firms will choose to open new plant locations in areas with less regulation. Similarly, if regulation impacts competitiveness, then there should be a positive correlation between regulation and net imports of an industry: as regulation increases, countries with more lax regulations will gain a great share of the import market. Further, if the pollution haven theory is to hold, then stringent regulation in the United States will induce high polluting firms to disproportionately invest overseas.

Though some economists have found a pollution haven effect, many economists have discovered that regulation has no negative impact on competitiveness, and some have even argued that regulation may increase competitiveness. Even in studies that have found that regulation hampers competitiveness, the effect tends to be insignificant or, at most, significant but relatively minor. A 1995 survey of economic studies by Jaffe et al., for instance, concludes that "overall, there is relatively little evidence to support the hypothesis that environmental regulations have had a large adverse effect on competitiveness, however that elusive term is defined."² Eban Goodstein not only corroborated

1. February 2006. This issue brief was written by Genevieve Smith, Regulatory Policy Analyst.

2. Jaffe et al., *Environmental Regulation and the Competitiveness of U.S. Manufacturing: What Does the Evidence Tell Us?*, 33 J. ECON. LIT. 132, 157 (1995).

Jaffe's conclusions but has also found that, between 1979-1989, the industries that spent more on regulation compliance actually exhibited superior performance compared to imports from developed and developing countries.³ Those who claim that regulation is overly burdensome tend to ignore the divergent economic opinion on regulation and competitiveness and instead focus only on inapposite evidence mischaracterized as corroborating a deregulatory agenda.

Regulation does not negatively impact plant location decisions.

The Jaffe et al. study looked at all three indicators of competitiveness and found on all accounts that regulation was not a major factor in competitiveness. In the case of plant location decisions, Jaffe et al. found that there is little evidence to support the conclusion that stringent regulation is a major determinant in plant location decisions. This finding is corroborated by a host of other economists. Timothy J. Batrik studied the impacts of state government environmental regulation expenditures on plant location decisions and found that such expenditures had an insignificant effect on plant locations.⁴ Kevin Gallagher found that plants moving to Mexico are not the ones with highest pollution abatement costs; overseas movement of industries is affected more by labor costs than by regulation.⁵ A look at plant location within India found that increased government spending on environmental regulation not only did not deter plant location but actually had a positive impact.⁶

Clark, Marchese, and Zarrilli examined industry decisions to conduct offshore assembly in developing companies. Consistent with the findings on plant location, the authors found that pollution intensive industries were less likely to conduct offshore assembly. They argued that the U.S. has a comparative advantage in highly polluting industries, while developing countries have a comparative advantage in simple assembly industries. At the same time, "the cost of pollution control and abatement are too small to influence the competitive performance of location decision of these activities."⁷

Regulation does not increase dependence on imports.

Further, several economic studies have found that stringent regulations have not led to

3. Eban Goodstein, *A New Look at Environmental Protection and Competitiveness*, Briefing Paper for the Economic Policy Institute, Washington, DC (1997).

4. Timothy J. Batrik, *The Effects of Environmental Regulation on Business Location in the United States*, 19 GROWTH CHANGE 22 (1988).

5. Kevin Gallagher, *Trade Liberalization and Industrial Pollution in Mexico: Lessons for the FTAA*, Working Paper for Global Development and Environment Institute (October 2000).

6. Muthukumara Mani, Sheoli Pargal & Mainul Huq, *Does Environmental Regulation Matter? Determinants of the Location of New Manufacturing Plants in India in 1994*, World Bank Working Paper, at 1-26.

7. Don P. Clark, Serafino Marchese & Simonetta Zarrilli, *Do Dirty Industries Conduct Offshore Assembly in Developing Countries?*, 14 INT'L ECON. J. 75, 86 (2000).

increases in imports. Jaffe et al. examined a number of studies on the impact of regulation on imports and exports and concluded once again that regulation has no significant impact. Grossman and Krueger, for instance, looked at the impacts of NAFTA on net imports and found greater imports in industries with the lower pollution costs. Moreover, they found that "traditional determinants of trade and investment patterns" have a significant impact on net imports while environmental costs have a minor and insignificant impact.⁸

A 1997 briefing paper by Eban Goodstein confirmed the findings of Jaffe et al. Moreover, Goodstein's study also found that "over the 1979-89 period, *industries that spend more money complying with environmental regulations actually demonstrated superior performance against imports from developed countries.*"⁹ Goodstein found the same relationship "for imports from developing countries, but the relationship was not as strong."¹⁰ Goodstein expanded on existing research on the effect of regulation on net imports by exploiting the large dataset made available by the National Bureau of Economic Research (NBER). Again, he concluded from the data that environmental regulation does not harm U.S. competitiveness. A look at the top 20 industries that experienced growth of import share by less-developed countries (LDC) from 1973-79 and 1979-89 shows that industries with high environmental costs were not the industries experiencing growth in net imports. In fact, "only three of the top 20 in the early period were industries with higher-than-average environmental costs; only one in the latter. It seems, then that low-wage industries, not 'dirty' ones, dominate the list of LDC import leaders."¹¹

Regulation does not send foreign investment abroad.

Despite predictions to the contrary, several economic studies have found foreign direct investment to increase with environmental stringency, implying that environmental regulation does not deter foreign investors. In a recently published article for the *International Trade Journal*, Elizabeth T. Cole and Prescott C. Ensign have found that U.S. FDI into Mexico is moving toward low polluting industries.¹² In fact, air pollution decreased in the United States at a time when foreign direct investment was increasing.¹³

8. Gene M. Grossman & Alan B. Krueger, *Environmental Impacts of a North American Free Trade Agreement*, in *THE US-MEXICO FREE TRADE AGREEMENT* 13 (Peter Garber ed. 1993).

9. Goodstein, *supra* note 3, at 2.

10. *Id.*

11. *Id.* at 6

12. Elizabeth T. Cole & Prescott C. Ensign, *An Examination of U.S. FDI into Mexico and its Relation to NAFTA: Understanding the Effects of Environmental Regulation and the Factor Endowments that Affect Location Decision*, 19 *INT'L TRADE J.* 1 (2005).

13. DAVID WHEELER, *RACING TO THE BOTTOM? FOREIGN INVESTMENT AND AIR POLLUTION IN DEVELOPING COUNTRIES* (Development Research Group, World Bank, 2001), available at <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=632594>. Wheeler's study shows a correlation and not causation.

Thus, the bulk of the economic literature contradicts the claim that regulation seriously hampers U.S. competitiveness. As Jaffe et al. conclude, "studies attempting to measure the effect of environmental regulation on net exports, overall trade flows, and plant-location decisions have produced estimates that are either small, statistically insignificant, or not robust to tests of model specification."¹⁴ Other economic factors, such as labor costs, play a much more significant role in the movement of industries. Concludes Goodstein, "Highly polluting industries are relocating to poor countries; but the reason, overwhelmingly, is low wages."¹⁵

Economic opinion on the existence of a pollution haven effect is by no means conclusive. Economic studies deviate broadly on the subject. According to one literature review, "much of the empirical literature that has attempted to test this assumption has arrived at differing conclusions, ranging from a modest deterrent effect of environmental regulatory stringency on economic activity to a counterintuitive modest attract effect."¹⁶ Even in the most damning characterizations, regulation still is only said to have a modest impact on U.S. competitiveness¹⁷

Even if *some* evidence does point to a pollution haven effect, one cannot dismiss the wide range of divergent economic opinion on the subject. As Tim Jeppesen, John List and Henk Folmer conclude in a 2002 article for the *Journal of Regional Science*, "casual perusal of the literature [on regulation and competitiveness] indicates that construction of a consensus point is akin to finding a needle in a haystack."¹⁸

2. Regulation does not cost jobs.

Economists have also refuted the claim that increased regulation decreases jobs. Economist Eban Goodstein at the Economic Policy Institute has written substantially on the relationship of jobs and the environment. According to Goodstein, the jobs-environment trade-off is largely a myth. Goodstein's book *Jobs and the Environment: The Myth of a National Trade-Off* finds a small positive effect of environmental regulation on overall employment, especially in the area of manufacturing

14. Jaffe et al., *supra* note 2, at 157-158.

15. EBAN GOODSTEIN, *JOBS AND THE ENVIRONMENT: THE MYTH OF A NATIONAL TRADE-OFF* 19(1994).

16. Smita B. Brunnermeier & Arik Levinson, *Examining the Evidence on Environmental Regulations and Industry Location*, 13 J. ENVT. & DEVEL. 6 (2004).

17. See Keller & Levinson, *Pollution Abatement Costs and Foreign Direct Investment Inflows to U.S. States*, 84 REV. ECON. & STATS. 691 (2002), in which they found that environmental regulation does have significant negative impact on FDI into the United States, but the magnitude is economically small. See also Arik Levinson, *Environmental Regulation and Manufacturers' Location Choices: Evidence from the Census of Manufacturers*, 62 J. PUB. ECON. 5 (1996), in which Levinson found that the manufacturing sector is sensitive to environmental regulation, but again the impact is small in magnitude. Though the sector was sensitive to regulation, "the degree of aversion to stringent states does not seem to increase for pollution-intensive industries."

18. Tim Jeppesen, John A. List, & Henk Folmer, *Environmental Regulations and New Plant Location Decisions: Evidence from a Meta-Analysis*, 42 J. REGIONAL SCI. 19, 36 (2002).

workers.¹⁹ Goodstein also finds that environmental regulation does not lead to manufacturing plant shutdowns.

Regulation leads to job creation and innovation of new technologies that can then expand the economy. Government spending on environmental regulation includes “investments in pollution control equipment and personnel, scientific studies to test pesticides and chemicals, the clean-up of hazardous wastes at Superfund sites, and the bill paid to your local garbage collector.”²⁰ All of these costs *create jobs*. Moreover, these jobs are overwhelmingly blue collar and, by nature, domestic.²¹ According to Goodstein, “the one comprehensive estimate available suggests that, in 1992, just under 4 million jobs were directly or indirectly related to pollution abatement and environmental protection the United States.”²²

Even the more equivocal work of Richard D. Morgenstern, William A. Pizer, and Jhih-Shyang Shih cannot avoid the job-creating potential of environmental protection: they conclude that environmental regulation is *just as likely* to create jobs as to cause job losses. “While environmental spending clearly has consequences for business and labor, the hypothesis that such spending significantly reduces employment in heavily polluting industries is not supported by the data,” they write.²³ Morgenstern et al. examined the pulp and paper, plastics, petroleum and steel sectors and found “that a million dollars of additional environmental expenditure is associated with an insignificant change in employment.”²⁴

They explain: “Most importantly, there are strong positive employment effects in industries where environmental activities are relatively labor intensive and where demand is relatively inelastic, such as plastics and petroleum. In others, where labor already represents a large share of production costs and where demand is more elasticity, such as steel and pulp and paper, there is little evidence of a significant employment consequence either way.”²⁵

Berman and Bui also found that regulation had no impact on labor demands. The authors examined the impact on labor demands of increased air pollution abatement in the Los Angeles area.

19. See generally Goodstein, *supra* note 15.

20. Eban Goodstein, *Jobs or the Environment? No Trade-Off*, 38 CHALLENGE 41, 46 (1995).

21. Frank Ackerman & Rachel Massey, *Prospering with Precaution: Employment, Economics, and the Precautionary Principle* (Precautionary Principle Project, Aug. 2002), available at <<http://www.healthytomorrow.org/pdf/prosper.pdf>>.

22. *Id.* at 42.

23. RICHARD D. MORGENSTERN, WILLIAM A. PIZER, & JHIH-SHYANG SHIH, *JOBS VERSUS THE ENVIRONMENT: AN INDUSTRY-LEVEL PERSPECTIVE* (Resources for the Future Discussion Paper No. 99-01-REV, 2000) 25.

24. *Id.* at 24.

25. *Id.*

In looking at data from 1979 through 1992, a period that saw sharp increases in environmental regulation, they found that increased regulation had no effect on employment in refineries.²⁶

3. Regulation can improve efficiency.

Those positing an anti-regulatory agenda are forced to dismiss entirely the Porter “hypothesis” that regulation can actually increase productivity by increasing the efficiency of operations. Porter’s theory was developed in response to real-world observations, such as OSHA’s Cotton Dust Rule, in which regulations to protect the public had indirect benefits of inducing technological innovations and improved efficiencies in business operations. Since Porter elaborated his argument, the real world examples have continued to multiply. His “hypothesis” is now backed by a robust body of empirical evidence:

- Though regulation certainly does result in some cost to industry, it can also spur economic growth and increased efficiency. Jaffe points to a 1990 Barbera and McConnell study that “found that lower production costs in the nonferrous metals industry were brought about by new environmental regulations that led to the introduction of new, low-polluting production practices that were also more efficient.”²⁷ EPA itself has in fact argued that environmental regulations generate “more cost-effective processes that both reduce emissions and the overall cost of doing business.”²⁸
- A study of the impacts on food manufacturing of trade liberalization between Mexico and the U.S. found that free trade would benefit Mexican producers because of resulting productivity growth, not because of the country’s more lax environmental regulation. In fact, increased environmental regulation actually stimulated greater productivity in Mexican food manufacturing. “Pollution abatement efforts encouraged by the Mexican Government’s inspection program manifestly have stimulated improvements in food processing efficiency as well as in environmental quality.”²⁹ The enhanced productivity offset any consequence for the profitability of Mexican food manufacturing in the aftermath of the new pollution controls. At the same time, the authors found “U.S. pollution regulations have had no impact on the

26. Eli Berman & Linda T. M. Bui, *Environmental Regulation and Labor Demand: Evidence from the South Coast Air Basin*, 79 J. PUB. ECON. 265 (2001).

27. Jaffe et al., *supra* note 2, at 155.

28. Office of Air and Radiation, Environmental Protection Agency, *The Clean Air Marketplace: New Business Opportunities Created by the Clean Air Act Amendments—Summary of Conference Proceedings* (July 24, 1992).

29. Ebru Alpay, Steven Buccola, & Joe Kervilet, *Productivity Growth and Environmental Regulation in Mexican and U.S. Food Manufacturing*, 84 AMER. J. AGR. ECON. 887, 894 (2002).

profitability or productivity of U.S. food manufacturing.”³⁰

- Berman and Bui also found that in meeting more stringent environmental standards, oil refineries in the Los Angeles Air Basin actually increased their productivity and efficiency. Interviews with “plant managers and environmental engineers suggested that productivity increases were not accidental. They resulted from a careful redesign of production processes induced by the need to comply with environmental regulation.”³¹
- Stephen Meyer compared regulation across states in the United States found that environmental regulation did impact economic prosperity. In fact, “states with stronger environmental regulations tended to have higher growth in the gross domestic products.”³² Though the correlation does not suggest causation, it does indicate that environmental regulation does not hinder state’s economies. The correlation held true even during times of recession. In an update focusing on the 1990-91 recession, Meyer found states with stronger environmental regulation were not more likely to face economic decline during a period of recession than states with weaker environmental standards.³³

Although the United States already has the least restrictive regulation in the world³⁴ and is third on the list of the world’s top ten economies,³⁵ the business community has continued to assert that health, safety and environmental regulation is overly burdensome and must therefore be repealed. Yet the evidence shows that the cost to business of complying with regulation is negligible and that factors such as wages and trade agreements have a far greater impact on the competitiveness of U.S. business or the choice of an industry to move business overseas.

30. *Id.* at 887.

31. Eli Berman & Linda T. M. Bui, *Environmental Regulation and Productivity: Evidence from Oil Refineries*, 83 REV. ECON. & STATS. 498, 508 (2001).

32. Stephen Meyer, *Environmentalism and Economic Prosperity: An Update* (Department of Political Science, Massachusetts Institute of Technology, Feb. 1993), at 2.

33. *Id.* at 9.

34. OFFICE OF INFO. & REG. AFFS., OMB, 2005 DRAFT ANN. REPT. TO CONG. ON COSTS & BENS. OF FED. REG. at 33 text accompanying note 22.

35. *Id.* at 30 text accompanying note 16.



**Testimony of Joan Claybrook, President, Public Citizen,
before the
Subcommittee on Regulatory Affairs of the
House Committee on Government Reform
*Submitted June 28, 2005***

Thank you, Ms. Chairman and members of the Subcommittee on Regulatory Affairs, for the opportunity to offer this testimony on the Office of Management and Budget's (OMB's) nominations to the U.S. Departments of Transportation and Labor that came out of its 2004 Report to Congress.

My name is Joan Claybrook and I am the President of Public Citizen, a national non-profit public interest organization with over 160,000 members nationwide. We represent consumer interests through lobbying, litigation, regulatory oversight, research and public education. I am also a former regulator, as the Administrator of the National Highway Traffic Safety Administration (NHTSA) in the Department of Transportation from 1977 to 1981. I have worked to improve motor vehicle safety for more than 40 years.

Today I would like to make three major points.

1. Well-designed health, safety and environmental protections stimulate the economy, result in better products and improve the overall quality of life.

We are here today because regulated industry, like most of us, would prefer not to be told what to do. The question is whether this dislike for rules is justified because it causes economic harm to industry or to all of us. While it may seem intuitive that regulations cost businesses and jobs, there is little actual research to suggest that this claim is true. There is in fact strong scholarship and empirical evidence to the contrary.

The industry mainly cites badly inflated and repackaged data from a flawed study by Crain and Hopkins, in which the data dates from 1990 and 1991.¹ The OMB cites a study by the World Bank and an economist from the Organization for Economic Co-operation and Development (OECD) that dealt with the constraints on capital under regulated economies -- including constraints on property and contractual rights.² Yet the U.S. is already the least restrictively regulated industrial country in the world.³ The OMB-cited studies do not address the economic consequences that might arise from

rollbacks of our existing, relatively robust and well-justified health, safety and environmental rules.

In fact, most of the evidence on environmental and safety protections points in the opposite direction. Just as pollution wastes resources, unchecked harm to society is a squandered opportunity to prevent injury or save lives. We all pay, in terms of higher insurance and medical costs, in lost worker productivity and illness, and even in traffic delays. As just one example, the annual cost of all traffic crashes in the U.S., which take more than 42,000 lives and inflict more than 3 million injuries every year, is more than \$230 billion in 2000 dollars, or \$800 for every man, woman and child in the U.S.

It is not mere conjecture that well-crafted and well-justified regulation spurs innovation and growth – it is fact. Regulation also enhances competitiveness and helps to ensure that industries are shielded from the often dire consequences of short-term, profit-driven decision making. For example, the fuel economy standards put in place while I was Administrator helped to shield the domestic auto industry from a disaster during the late 1970s domestic oil crisis, created jobs in more sustainable technologies, insulated fuel costs from inflation-inducing spikes and reduced harmful pollution.

The literature on manufacturing competitiveness and regulation, and core insights from my 40 years of participation in the regulatory process, shows that well-designed rules can improve economic well-being in the following ways:⁴

- **It is far cheaper to prevent harm than to clean up afterwards.** Regulation that corrects market failures and requires the internalization of costs that would otherwise be inflicted on society turns a failure into a win-win. The innovation that it stimulates often results in cleaner, higher quality products with more consumer appeal and export value, and creates new industries and jobs (*i.e.*, in recycling, manufacturing pollution abatement technologies, antilock brakes, or air bags). Rules that internalize the real costs of activities connect cause with effect, focus attention on mitigation at the source, and generate useful information about inefficiencies. While in theory this brings the price of goods closer to the actual resource costs, in practice it often does even better by stimulating greater efficiencies – both improving quality and reducing harm.
- **Stimulating investment in sustainable practices is a core government function that also benefits industry.** According to the “Porter hypothesis,” a theory authored by Michael Porter of Harvard’s Kennedy School of Government which posits that well-crafted regulations lead to economic growth, the stimulation effect is far greater when regulations are more rather than less stringent. This is because growth from such “innovation offsets” can encourage true progress: extraordinarily creative measures which leap-frog industrial practices to new levels of quality, utility, environmental responsibility and societal well-being. To the extent that OMB’s meddling introduces unjustified uncertainty into the regulatory process, its actions can incur additional delay and unwarranted costs in the form of investment insecurity, undermining these benefits.

- **Regulation levels the playing field and reduces total societal costs for beneficial innovations.** Rolling back regulations, or not implementing appropriate regulations, unfairly imposes costs on the public. In contrast, rules that set minimum motor vehicle safety standards, for example, assure that the safety investment will be made by every manufacturer, and that suppliers will compete to bring down costs over time. These cost reductions can happen quickly and be quite dramatic. In the case of air bags, according to testimony by Fred Webber of the Alliance of Automobile Manufacturers at a hearing last week in the House Energy and Commerce Committee, the cost of frontal air bags fell from \$500 in the early 1990s to “well below \$100” today. The public and industry both benefit from far greater economies of scale when optional equipment becomes standard. For example, while side impact air bags can cost as much \$500 today, government estimates for side impact air bags as standard equipment in the near future are in the \$120 per vehicle range, including automaker and dealer profit.
- **As OMB concludes, health, safety and environmental rules are beneficial on balance.** While much of industry’s complaints focus on costs alone, every accounting report by OMB has found that regulations on the whole produce benefits that exceed costs by over threefold.⁵ This is remarkable, as OMB’s accounting of benefits ignore many unmonetized and qualitative benefits.

The assault on regulation is a convenient lobbying strategy: it is far easier to blame the rules than deal with the truth. A wealth of research shows that direct labor costs, such as the wages for comparably skilled workers, are the major driver for industrial decisions to relocate jobs, not regulatory costs, which are less than one percent of the cost of shipped goods.⁶ A closer look at recent history tells us there is little merit to industry’s claims that manufacturing rules are the cause of recent job losses in the manufacturing sector.

While these losses are both devastating and pervasive, very few new major regulatory burdens have been added to the manufacturing sector since 2000. In short, job losses have skyrocketed while the level of regulatory compliance has remained essentially unchanged since the mid-1990s, which was a time of record economic gains. It thus makes no sense to blame regulatory burdens for changes more likely attributable to fundamental shifts in the U.S. and global economy since 2000.

It appears far more likely from the literature and recent events that free trade agreements and tax loopholes encouraging foreign investment are the cause for industry job flight, as corporations seek out countries offering the lowest wages for workers. For example, a major study by the Economic Policy Institute shows that between 1993 and 2002, the North American Free Trade Agreement (NAFTA) resulted in a net loss of 879,280 American jobs.⁷

2. OMB’s 2005 Draft Report lacks objectivity and balance.

What is the sound of one hand clapping? OMB has more than earned the skepticism and antipathy of the public interest community by repeatedly publishing drafts

and final reports that make no mention of the serious objections submitted in comments to it. It is frustrating for regulatory experts who raise principled, well-documented critique, to receive no response, or even acknowledgment, from OMB regarding their potent analysis.⁸

This is in sharp contrast to the regulatory agencies, which must respond to comments under the Administrative Procedures Act in regulatory preambles. It is a miscarriage of OMB's assignment to conduct a notice and comment process on the draft versions of its report, yet never to actually respond to the arguments and facts presented. The outcome is a sloppy report, developed in a self-imposed vacuum, that provides little meaningful insight into crucial questions about regulatory needs.

The uncorrected flaws and omissions pointed out in comments but largely ignored by OMB are evidence of OMB's anti-regulatory bias and include the following:

- **Some rules in, others out.** OMB's decision to limit analysis of costs and benefits to a 10-year window is arbitrary. A regulation does not arbitrarily stop producing costs and benefits when it falls out of the temporal scope of OMB's analysis. For example, a range in benefits from \$433 million to \$4.4 billion with costs of \$297 million flowing from an EPA rule on acid rain (NOx) reductions, was excluded from the 2005 draft as untimely. OMB's 2005 draft also cherry-picked the specific rules included for analysis, presenting monetized costs and benefits for only 11 of its embarrassingly small ten-year total of 26 major rules.⁹ The report's accounting omits all homeland security rules, as well as what OMB nonsensically designates as "transfer rules."¹⁰ Adding to the incoherence, OMB admits to serious difficulty in aggregating cost and benefit estimates from different agencies, which apply different assumptions over different time periods.¹¹
- **Some studies in, others ignored.** OMB again neglected recent publications and studies detailing serious flaws in its current cost-benefit analysis practices, including several seminal look-back studies previously submitted to OMB by Public Citizen.¹²
- **Structural and informational flaws in cost-benefit analysis disregarded.** While cost estimates are inflated by industry sources, benefits information is underfunded, lacking or incomplete. Static cost projections prior to a rule's implementation usually become inaccurate over time as costs decline significantly, and innovations reduce compliance costs. Agencies also fail to factor in off-setting economic gains resulting from regulation-spurred innovation and growth in sustainable industries.
- **Costs and benefits of deregulatory actions utterly omitted.** OMB's single-edged sword fails to count lost benefits suffered by the public when safeguards are weakened or blocked, such as the Environmental Protection Agency's crippling of the New Source Review program under the Clean Air Act. The neglect of these costs to the public in OMB's report misrepresents the true costs of the failure to regulate effectively.
- **Ethical problems invalidate attempts to monetize the value of human life.** OMB's random assignment of a \$6.1 million value to a human life is grounded in dubious and totally discredited research on willingness-to-pay for risk reductions by

outdated studies of workers in high-risk jobs.¹³ This habit, and the discounting of life that accompanies it, are both morally offensive and intellectually bankrupt.

- **Information gaps and uncertainties are compounded by macro-level attempts to compute overall costs and benefits.** Without answering the criticism already addressed to OMB's overly simplistic accounting methods, the 2005 draft report solicits comments on a "net benefits" approach which would conceal lost opportunities to significantly increase benefits for a minimal increase in costs and would even further diminish the already questionable value of OMB's conclusions.

Finally, OMB's role directly conflicts, in many cases, with authorizing mandates agencies receive from Congress. For many workplace health, safety and environmental protections, as the Supreme Court has recognized, cost-benefit analysis in standard-setting is forbidden or is not an authorized basis for a standard.¹⁴

OMB's drive to impose cost-benefit analysis may stem from a confusion about the difference between decisions about *means* and decisions about *ends*. Cost-benefit analysis may be helpful in order to develop the most cost-effective *means* for carrying out a policy. In contrast, it is unethical to set the ends or goals for safeguards based upon any other factor than their impact on human health and well-being.

3. OMB's "hit list" is an inappropriate interference in agency functions.

There are two fundamental hypocrisies in OMB's interference in agency activities in the form of the "hit list," a process initiated by Office of Information and Regulatory Affairs (OIRA) Administrator John Graham that would irrationally discard those rules most disliked by industry:

- 1) The nomination and selection process for OMB's hit list lacks the minimum indicia of accountability and transparency that it would reasonably expect of any agency process; and
- 2) Its unwarranted and unauthorized interference in agency and Congressional priorities is unsupported by any analysis of the costs and benefits of the regulatory rollback it recommends or of the harm caused by delay in agency issuance of important new rules.

The consequence of these two flaws is that OMB's list is intellectually incoherent. OMB's choices for the hit list remain unexplained and unjustified. When OMB summarized the original 189 submissions in December 2004, it stated that it would instruct agencies to review the suggestions and respond. OMB then summarily announced the 76 hit list endorsements, without revealing any of the rationales for the presence of these on or off the list or the responses of the relevant agencies. OMB merely repeated the reasons offered by nominators in the first instance. The public deserves to be informed of the reasons for prioritizing these suggested rollbacks of their safeguards.

OMB also must justify the need for this process in view of the many other ways in which special interests can and do affect regulatory policy, which include petitions for rulemaking, comments to regulatory dockets, lobbying Congress, litigation and the direct lobbying of agencies. Instead, the hit list process lacks any disclosure where it counts most – OMB’s substantive decision making about priorities.

While OMB may attempt to cast this process as a method for unearthing long-neglected and commonsense regulatory “fixes,” at least two of the matters highlighted in testimony today, the hours-of-service rule and the hexavalent chromium rule, are the subject of ongoing agency rulemakings that have been pending for more than a few years. OMB does not explain why the rulemaking processes of agencies, as well as, in the case of hexavalent chromium, a review process initiated by the Small Business Administration, are insufficient to address the industry’s concerns.

Moreover, OMB must provide a good reason for its provision of yet another special access porthole in view of the tremendous and uneven power that regulated interests already have to weaken and derail regulation. The public, with only a relatively diffuse interest in the outcome of particular rules, is systematically disadvantaged by high-level attempts to highjack public priorities. OMB’s dabbling only exacerbates this profound inequality.

Leaving agenda-setting to Congress and the agencies makes much more sense. Congress is available to identify emerging public policy issues and to direct agencies to act, while the agencies know their issues with a depth and breadth that a handful of economists and a scientist or two at OMB cannot match. The courts also play a constitutionally assigned oversight role in safeguarding Congressional intent and assuring that evidence presented in the regulatory docket drives agency action.

While regulations may end up being far from perfect, the point is that the process involves a carefully designed balance, embedded in the separation of powers, and that OMB’s interference has no place in this purposeful architecture. OMB’s sole appropriate function is to assist in the coordination of delegated authorities among the agencies. It should not be a political gatekeeper or provide an appeal of last resort to derail rules for corporate interests.

Public Citizen’s 2004 comments called OMB to task for focusing on creation of a hit list rather than on unmet health safety and environmental needs. To that end, we submitted recommendations for affirmative action on 32 pressing social problems. OMB’s misappropriation of two of our nominations for its hit list does not alleviate the process deficiencies outlined above. While both of our rulemaking actions now on its hit list are legitimate areas for action by NHTSA, OMB fails to explain its rejection of our 30 other nominations, all of which were equally deserving of attention by NHTSA or another agency. This committee should direct OMB to explain its reasons for rejecting or accepting candidates for its hit list and to publicly share agency responses.

We were somewhat surprised to note that OMB appears to agree with our assessment that a motor vehicle compatibility standard is needed, and that voluntary manufacturer activity to address vehicle mismatch in crashes is insufficient. Vehicle compatibility is a long-neglected area. The design of light trucks — and large SUVs and pickup trucks in particular — with a high center of gravity, high bumpers, and steel bars and frame-on-rail construction, makes these vehicles highly aggressive in crashes.

A car driver is twice as likely to die if their vehicle is struck on the driver's side by an SUV rather than by another car. A vehicle compatibility standard is needed to mitigate harm done by aggressive vehicle designs. In addition, a consumer information program for an incompatibility rating would allow consumers to make more ethical decisions about the likely harm inflicted on others when purchasing a vehicle. Rather than pushing for these needed items, OMB appears content with NHTSA's promise to publish a report on this issue. This certainly ranks among the most tepid responses by any agency to a hit list prompt, and is far from good enough.

A requirement for an occupant ejection safety standard is pending in the Senate version of H.R. 3, the highway reauthorization bill and has received widespread bipartisan support. More than 13,000 highway fatalities involve ejection each year. Government estimates are that advanced glazing in side windows would save between 500 and 1,300 people each year, while stronger door locks and latches would prevent hundreds of deaths annually. Especially troubling is the fact that safety belts are not designed to protect occupants in rollovers, and more than 400 belted occupants are killed annually in rollover ejections.

We strongly support Congressional enactment of a requirement for a new ejection prevention safety standard, particularly when combined, as it is in H.R. 3, with a new standard for roof crush. A strong roof crush rule could dramatically reduce ejections by closing the ejection portals caused by roof deformation and broken side window glass.

Two of the other hit list nominations to be discussed today fall more squarely into OMB's typical anti-regulatory approach. In the case of both the hours-of-service and hexavalent chromium rules, court involvement initiated by Public Citizen was required to assure that the federal agencies act according to their statutory mandate. Also in both cases, Public Citizen's litigation was founded on a science-based challenge, and our claims were upheld by the reviewing court, U.S. Courts of Appeal in rulings by a three-judge panel.

I will address the hours of service rulemaking first. In 2003, Public Citizen sued the Federal Motor Carrier Safety Administration (FMCSA) over a final rule extending allowable driver time from 10 to 11 hours and for other serious flaws that diminished safety. The overall impact of the various parts of the overturned rule was to increase total work time by nearly 40 percent and total driving time by 20 percent.

A U.S. Court of Appeals for the District of Columbia Circuit overturned the rule, harshly criticizing FMCSA for failing to consider the effect of the rule on the health of

truck drivers as well as other challenged aspects of the rule. The Court strongly suggested that the agency's rule was not founded in science, which shows an increase in risk every hour of driving beyond eight hours on the road. The agency is now in rulemaking to respond to the court's decision.

Truck drivers are currently exempt from the Fair Labor Standards Act, and receive no overtime pay despite having to work 14-hour shifts – nearly double the daily hours of the average American. Truck driving is very strenuous work, involving operating a heavy vehicle for long periods of time, as well as unloading and loading shipments. Motor vehicle crashes involving commercial trucks kill nearly 5,000 Americans each year,¹⁵ and many of these crashes are fatigue-related.¹⁶

OMB's endorsement of a nomination to extend maximum driving time from 10 to 11 hours is entirely without basis in science and would greatly jeopardize the safety of both the public and commercial drivers. As FMCSA acknowledges in its rulemaking, performance degrades geometrically after eight hours, and in fact, the risk of a crash *doubles* between the 10th and 11th hours of consecutive driving.¹⁷

The local or short-haul drivers that are the focus of OMB's hit list item are not exempt from the cumulative fatigue of these long work shifts. Although fatigue effects for these workers may be relatively less severe when compared to long-haul drivers, long on-duty hours, regardless of driving time, still degrade performance and increase risk. One major study by FMCSA of short-haul drivers found that fatigue was a factor in 20 percent of the 77 critical incidents over a two week period where the driver was deemed at fault.¹⁸ Studies show that the overall impact of long work shifts negatively impacts safety, with risk approximately doubling after 12 hours of work.¹⁹ Long work days are exhausting, in and of themselves, and allowing drivers to continue driving at the tail-end of these long shifts merely would exacerbate risks to others on the road.

OMB's inclusion of OSHA's hexavalent chromium rulemaking on its list is similarly unjustified. All reputable scientists agree that hexavalent chromium is a lung carcinogen. The National Institute for Occupational Safety and Health in 1975, the National Toxicology Program in 1980, the Environmental Protection Agency in 1984, the International Agency for Research on Cancer in 1990 and the Agency for Toxic Substances and Disease Registry in 2000 have all reached this conclusion. So has OSHA itself. In 1994, in response to a petition from Public Citizen and a union now allied with the United Steelworkers to reduce occupational hexavalent chromium exposure levels, Joseph Dear, then Assistant Secretary of Labor for Occupational Safety and Health, stated that there is "clear evidence that exposure ... at the current [Permissible Exposure Limit] PEL ... can result in an excess risk of lung cancer."

Because of OSHA's failure to act on this conclusion, we sued the agency in 1997 and again in 2002. We prevailed in the second case, resulting in a court order from the U.S. Court of Appeals for the Third Circuit that OSHA produce a final rule by January 18, 2006. The court decried OSHA's "indefinite delay and recalcitrance in the face of an admittedly grave risk to public health" and held that "OSHA's delay in promulgating a

lower permissible exposure limit for hexavalent chromium has exceeded the bounds of reasonableness.”

On October 4, 2004, OSHA produced its court-ordered proposed rule, reducing the PEL from the current 52 micrograms to 1 microgram per cubic meter. In general, this rule is thoughtfully assembled, and comprehensively analyzes all data available to the agency. OSHA acknowledges that its new PEL leaves “clearly significant” health risks; we believe that it is economically and technologically feasible to lower the PEL still further to reduce these risks.²⁰ Based on the leading epidemiological study in the field (the Gibb study), exposure to hexavalent chromium at the current PEL of 52 micrograms per cubic meter for a working lifetime (the required assessment under the Occupational Safety and Health Act) would result in 351 excess lung cancer deaths per 1,000 workers. Even at the proposed PEL, nine excess lung cancer deaths per 1,000 workers would occur, well in excess of the standard set in the Supreme Court’s 1980 *Benzene* decision. At present, the agency estimates that over 85,000 workers (22.4 percent of chromium-exposed workers) exceed the proposed PEL.

The industry has already made full use of its numerous opportunities to influence this rulemaking. Through individual chromium-using companies, industry associations and the so-called Chrome Coalition, the industry intervened in both lawsuits, provided written comments during the three stages of the rulemaking, testified and cross-examined witnesses at a ten-day OSHA public hearing, participated in the Small Business Regulatory Enforcement Fairness Act (SBREFA) process, and held at least two meetings with the OMB. The chromium industry testimony in this hearing is simply the latest round in an effort, stretching back over a decade, to undermine a proposed rule that could save hundreds of lives.²¹

It is not as if OSHA has been too busy to regulate hexavalent chromium. The agency has not completed a single regulation on an occupational chemical since 1997 and, except for this court-ordered proposal, has not proposed any such regulation since at least the beginning of the Clinton administration. There is little else of substance on the agency’s regulatory agenda at present.

Conclusion: OMB misses the point.

Regulations are a modern form of the social contract. They embody a fundamentally democratic idea about the exchange of responsibilities among participants in a society. The expression of values and moral judgments enacted by government safeguards are completely neglected in OMB’s econometric accounting of what government is or does.

To illustrate the depth of commitment and salience of the common sentiments captured in government standards, I'd like to suggest the following five principles for understanding the purposes of government regulation. These are my own version of the ideals at stake in debates over the nature of the regulatory process and decisions about whether and how to regulate:

- 1) Corporations, like people, should clean up after themselves and be required to prevent the foreseeable harm of actions and choices.
- 2) Government action should correct social and political wrongs, set out fair rules for participation, distribute resources fairly and preserve and protect shared resources and the public commons.
- 3) Government activity both reflects and enacts moral values and collective goals – clarifying who we are and what matters to us.
- 4) People have a responsibility to actively respect the lives and health of people we do not know, as well as the natural environment and its limitations and gifts.
- 5) Voluntary risks are morally distinct from risks imposed upon the public without their knowledge or consent.

The principles encapsulate some of what is systematically disregarded by OMB's cynical view of both government and the people whom government protects under the constitutional prescription that it "promote the general Welfare."

Because much government activity is motivated by equitable concerns for others, rather than narrow self-interest, OMB's basic framework excludes a real understanding of its subject. Members of Congress, on the other hand, must be responsive to the human concerns that animate government action. They therefore should recognize the crippling limitations of OMB's analytical tools and worldview.

Endnotes

¹ In a hearing in 2003, Graham thoroughly dismissed the Crain and Hopkins study regularly cited by industry, stating:

“The fact that attempts to estimate the aggregate costs of regulations have been made in the past, such as the Crain and Hopkins estimate of \$843 billion mentioned in Finding 5, is not an indication that such estimates are appropriate or accurate enough for regulatory accounting. Although the Crain and Hopkins estimate is the best available for its purpose, it is a rough indicator of regulatory activity, best viewed as an overall measure of the magnitude of the overall impact of regulatory activity on the macro economy. The estimate, which was produced in 2001 under contract for the Office of Advocacy of the Small Business Administration, is based on a previous estimate by Hopkins done in 1995, which itself was based on summary estimates done in 1991 and earlier, as far back as the 1970s. The underlying studies were mainly done by academics using a variety of techniques, some peer reviewed and some not. Most importantly, they were based on data collected ten, twenty, and even thirty years ago. Much has changed in those years and those estimates may no longer be sufficiently accurate or appropriate for an official accounting statement. Moreover, the cost estimates used in these aggregate estimates combine diverse types of regulations, including financial, communications, and environmental, some of which impose real costs and others that cause mainly transfers of income from one group to another. Information by agency and by program is spotty and benefit information is nonexistent. These estimates might not pass OMB’s information quality guidelines.”

Hearing on H.R. 2432, Paperwork and Regulatory Improvements Act of 2003, July 22, 2003, Transcript at 21 (statement of John Graham). Nonetheless, the 2005 Draft Report refers to this study without further qualification. See Office of Info. & Reg. Affs., OMB, 2005 Draft Ann. Rept. on Costs and Benefits of Fed. Regs. (hereinafter “Draft Report”) (calling the Crain and Hopkins study a “recently sponsored . . . study” proving a disproportionate burden on small businesses).

² The Center for Progressive Reform (CPR) highlighted in comments last year to the 2004 draft report that OMB relied upon flawed and inapposite studies to support its claim of a regulation-economic strength trade-off. See Heinzerling, Lisa and Frank Ackerman, Letter to Lorraine Hunt, OIRA, May 20, 2004, at 4. OMB repeats this mistake in this year’s draft report, citing the same flawed and inapposite studies, such as the Heritage Foundation index. OMB states that “[s]ince 1995, the Heritage Foundation and the *Wall Street Journal* have published jointly a yearly index of economic freedom for 161 countries. They find a very strong relationship between the index and per capita GDP.” OMB Draft report, at 30. OMB uses the Heritage Foundation index in support of the “impact of smart regulation on economic growth,” even while acknowledging that a “correlation between degrees of economic freedom and per capita GDP does not prove that economic freedom causes economic growth.” *Id.* OMB also cites an index published by the Fraser Institute, which CPR also criticized in comments to the 2004 draft report. OMB uses both the Heritage Institute and the Fraser Institute indexes, even though, according to OMB, both “have several drawbacks,” such as “the data are based largely on subjective assessments and survey results” and “include non-regulatory indicators.” Additionally, OMB cites a World Bank study despite an extensive critique of OMB’s use of the report last year by CPR that showed the report’s conclusion to be inapplicable to OMB’s purposes.

³ OMB, “Draft 2005 Report to Congress on the Costs and Benefits of Federal Regulations,” at 33.

⁴ The leading article in this line of study is the justly famous Michael E. Porter & Claas van der Linde, *Toward a New Conception of the Environment-Competitiveness Relationship*, 9 *J. Econ. Perspectives* 97 (1995). Other important studies include the following: Ebru Alpay, Steven Buccola & Joe Kervilet, *Productivity Growth and Environmental Regulation in Mexican and U.S. Food Manufacturing*, 84 *Amer. J. Agr. Econ.* 887 (2002) (finding that Mexican food manufacturers developed improved efficiencies in operations as a result of increasing stringency of environmental regulation); Eli Berman & Linda T.M. Bui, *Environmental Regulation and Productivity: Evidence from Oil Refineries*, 83 *Rev. Econ. & Stats.* 498 (2001) (finding that L.A. Air Basin oil refineries achieved improved operations directly because of heightened environmental standards); Eban Goodstein, *Polluted Data*, *Amer. Prospect*, Nov.-Dec. 1997, at 64 (charting many cases in which regulations resulted in innovations that significantly offset the initial cost of compliance); Stephen Meyer, *Environmentalism and Economic Prosperity: An Update* (MIT, Feb. 1993) (finding that states with stronger environmental protections tended to have higher GDP growth than states

with laxer regulation); Office of Tech. Assessment, U.S. Cong., Gauging Control Technology and Regulatory Impacts in Occupational Safety and Health: An Appraisal of OSHA's Analytical Approach (Rep. No. OTA-ENV-635, Sept. 1995), available at <http://www.wws.princeton.edu/~ota/disk1/1995/9531_n.html>.

⁵ OMB, Draft 2005 Report to Congress on the Costs and Benefits of Federal Regulations, at 4.

⁶ See generally Kevin Gallagher, Trade Liberalization and Industrial Pollution in Mexico: Lessons for the FTAA (Global Dev. & Env't. Inst. Working Paper, Oct. 2000) (finding that labor costs rather than pollution abatement regulation drive overseas relocation of industries); Eban Goodstein, A New Look at Environmental Protection and Competitiveness (Econ. Pol. Inst. Briefing Paper, 1997) (concluding that industries that spent more on regulatory compliance between 1979-1989 exhibited superior performance to foreign competitors); Eban Goodstein, Jobs and the Environment: The Myth of a National Trade-Off 19 (1994) ("Highly polluting industries are relocating to poor countries; but the reason, overwhelmingly, is low wages."); Jaffe et al., *Environmental Regulation and the Competitiveness of U.S. Manufacturing: What Does the Evidence Tell Us?*, 33 J. Econ. Lit. 132 (1995) (finding that "overall, there is relatively little evidence to support the hypothesis that environmental regulations have had a large adverse effect on competitiveness"). See also Testimony of Sidney A. Shapiro, before the Subcommittee on Regulatory Affairs Committee on Government Reform, U.S. House of Representatives, April 12, 2005.

⁷ Scott, Robert E., "The High Price of 'Free' Trade: NAFTA's Failure Has Cost the United States Jobs Across the Nation," November 17, 2003, Economic Policy Institute Briefing Paper #147.

⁸ For just one example of this imperviousness, OMB claimed in the 2005 draft report that the costs associated with regulations is borne by workers, providing no support for this strong claim except for a citation to a single economics textbook. In its 2004 comments, CPR excoriated OMB for this thinly veiled and inaccurate attack on regulation, stating: "Textbooks, of course, do not all agree with each other, and they do not represent peer-reviewed literature, the standard of proof that OMB requires in other areas. OMB cites no empirical evidence for its claim. OMB should exclude this claim from the Report unless it produces evidence for it. Moreover, if OMB does produce evidence for this claim, it should address the significant evidence that exists on the other side of the issue. For example, University of California-Berkeley economist David Card and Princeton University economist Alan Krueger have written widely on empirical studies of minimum wage laws, finding that - contrary to assumptions in many textbooks - moderate increases in the minimum wage have a zero to slightly positive effect on employment. Their work has appeared twice in the prestigious *American Economic Review*, and the book-length version has been published by Princeton University Press." Heinzerling, Lisa and Frank Ackerman, Letter to Lorraine Hunt, OIRA, May 20, 2004, at 3. Regardless of this well-reasoned objection, OMB's 2005 draft report repeated the assertion verbatim and without noting CPR's critique.

⁹ OMB, "Draft 2005 Report to Congress on the Costs and Benefits of Federal Regulations," at 6. This year's draft report lists only 26 major rules, of which 15 lack fully quantified costs, benefits, or both. Eight of those 15 state that the benefits are unquantifiable "homeland security" benefits, which OMB declares are simply too hard to quantify. (Two of those are food safety regulations securing the food supply against bioterror.) The remaining seven are a grab bag of protective policies and deregulation decisions, which include protections against mad cow disease (which lacks benefits estimates, because "the exact quantitative relationship between human exposure to the [mad cow disease] agent and the likelihood of human disease is still unknown"); a rule implementing a ban on trade with Syria while it continued to occupy Lebanon (which lacks benefits estimates); two regulations of migratory bird hunting (lacking cost estimates); the controversial rollback of overtime rights (which lacks benefits estimates and does have cost estimates, although it excludes an estimated 6 million workers who could lose overtime protections); and the regulation of computerized reservation systems for travel agents.

¹⁰ As CPR pointed out in 2004 comments in a critique which went unanswered by OMB, the designation by OMB of some rules as transfer rules makes little sense. One so-called "transfer rule" is of particular interest, as it concerns a rule currently being challenged in court by Public Citizen. The rule allocates credits under the Corporate Average Fuel Economy (CAFE) program to automakers for the production of vehicles with a "dual-fuel" capacity. Because these vehicles actually use alternative fuel less than 1 percent of the time, according to the government's own published estimates, the rule permits overall fuel economy standards to be considerably lower than those set under CAFE. There are few clearly quantifiable public benefits and no monetizable benefits, according to NHTSA's regulatory impact analysis (RIA) on the subject, which also provides a cost estimate range for the rule as between 2.6 billion and 3.2 billion gallons

of gasoline, at a corresponding discounted value of between \$1.9 billion and \$2.2 billion. See "Final Economic Assessment, Alternative Fuel ed Vehicles, Extension of CAFE Option, Part 538," Feb. 2004, Docket No. NHTSA-2001-10774-37. OMB has therefore designated a "transfer rule" a rule that has nothing to do with the budget, that NHTSA clearly thought required preparation of an RIA, and for which NHTSA estimated massive costs and only highly contingent, and possibly nonexistent, benefits.

¹¹ OMB, "Draft 2005 Report to Congress on the Costs and Benefits of Federal Regulations," at 39.

¹² Overlooked studies included: Thomas O. McGarity & Ruth Ruttenberg, *Counting the Cost of Health, Safety, and Environmental Regulation*, 80 Tex. L. Rev. 1997, 2030-33(2002); Ruth Ruttenberg & Assocs., Public Citizen, Not Too Costly After All: An Examination of the Inflated Cost-Estimates of Health, Safety, and Environmental Protections, Feb. 2004 (available on-line at <http://www.citizen.org/documents/Not%20Too%20Costly.pdf>); Frank Ackerman & Lisa Heinzerling, *Pricing the Priceless: Cost-Benefit Analysis of Environmental Protection*, 150 U. PA. L. Rev. 1553, 1554 (2002). Lisa Heinzerling and Frank Ackerman, *Priceless: On Knowing the Price of Everything and the Value of Nothing*, New Press, Jan. 2004; Richard W. Parker, *Grading the Government*, 70 U. Chi. L. Rev. 1345 (2003).

¹³ See Lisa Heinzerling and Frank Ackerman, *Priceless: On Knowing the Price of Everything and the Value of Nothing*, New Press (2004) at 75-6 (providing ample discussion of the grave deficiencies in willingness-to-pay calculations, including its basis in studies rife with methodological problems); see also Heinzerling, Lisa and Frank Ackerman, Letter to Lorraine Hunt, OIRA, May 20, 2004.

¹⁴ See *American Textile Manufs. Inst. v. Donovan*, 452 U.S. 490 (1981) (Cotton Dust case); *AFL-CIO v. American Petrol. Inst.*, 448 U.S. 607 (1980) (The "Benzene Case").

¹⁵ National Highway Traffic Safety Administration, "2004 Projections: Motor Vehicle Traffic Crash Fatalities and Injuries," Washington, D.C.: NHTSA, Apr. 21, 2005, at 33.

¹⁶ The National Transportation Safety Board has estimated driver fatigue as a probable cause in 58 percent of single-vehicle large truck crashes it investigated and 30 to 40 percent of all large truck crashes. See National Transportation Safety Board, "Factors That Affect Fatigue in Heavy Truck Accidents," Washington, D.C.: NTSB, 1995, at v.

¹⁷ Federal Motor Carrier Safety Administration; Notice of Proposed Rule: Hours of Service of Driver, Drivers Rest and Sleep for Safe Operations; Docket No.FMCSA-97-2350-972; Washington, D.C.: FMCSA; May 2, 2000; at 25544.

¹⁸ The study involved 42 drivers only and classified 77 of the total 249 critical incidents recorded as the fault of the driver. See *Impact of Local/Short Haul Operations on Driver Fatigue*, U.S. Department of Transportation, Federal Motor carrier Safety Administration, Report No. DOT-MC-00-203, Sept. 200, at ix.

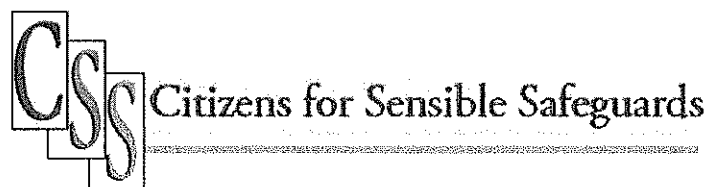
¹⁹ S. Folkard, "'Time On Shift Effects' In Safety: A Mini-Review," Abstract in the *Shiftwork International Newsletter*, May 1995, 12:1, Timothy Monk, ed., presentations from the 12th International Symposium On Night- and Shiftwork, Ledyard, CN, June 13-18, 1995. Multiple studies show that working past the 11th hour of a shift decreases performance and alertness. Additionally, long hours can lead to further decreased sleep time, as sleep is sacrificed to perform personal activities, and the cumulative effect of long hours can lead to unresolved sleep debt. See Roger Rosa and Michael Colligan, "Extended Workdays: Effects of 8-Hour and 12-Hour Rotating Shift Schedules On Performance, Subjective Alertness, Sleep Patterns, and Psychological Variables," *Work and Stress*, 1989, 3:1, 21-32; Roger Rosa and Michael Colligan, "Extended Workdays: Effects of 8-Hour and 12-Hour Rotating Shift Schedules On Performance, Subjective Alertness, Sleep Patterns, and Psychological Variables," *Work and Stress*, 1989, 3:1, 21-32; and Roger Rosa and Michael Bonnet, "Performance and Alertness On 8 H and 12 H Rotating Shifts At a Natural Gas Utility," *Ergonomics*, 1993, 36:10, 1177-1193.

²⁰ Gibb HJ, Lees PSJ, Pinsky PF, Rooney BC. "Lung cancer among workers in chromium chemical production," *Amer. J. of Industrial Med.* 2000; 38:115-26.

²¹ The timeline for efforts to establish rules for hexavalent chromium exposure is as follows:

- o **July 1993** - Public Citizen files a petition for a rulemaking for an occupational health standard for hexavalent chromium.
- o **Feb. 1994** - OSHA agrees there is clear evidence of an excess risk of lung cancer with exposure at the existing standard, and states that it will publish a notice of proposed rulemaking no later than March 1995.
- o **Aug. 1997** - After repeated delay in issuance of a notice (accompanied by repeated acknowledgments that the existing standard was inadequate and should be lowered by a factor of

-
- 10 to 100), OSHA denies Public Citizen's request for a rulemaking schedule but says it will move as quickly as possible.
- **Oct. 1997** - Public Citizen brings an action in the Third Circuit claiming unreasonable delay and seeking to compel action. OSHA tells the court that the agency expects to issue a notice of proposed rulemaking (NPRM) by Sept. 1999.
 - **March 1998** - The court denies the Public Citizen petition to compel agency action, holding that agency delay is not yet extreme enough to warrant action and emphasizing the agency's intention to act in 1999.
 - **August 2000** - The Gibb study is published and confirms that hexavalent chromium causes lung cancer at exposure levels far below those permitted by the existing standard.
 - **Dec 2001** - OSHA's regulatory agenda demotes revision of hexavalent chromium to a "long-term action" with a timetable "to be determined."
 - **March 2002** - Public Citizen files another action in court, claiming unlawful delay.
 - **December 2002** - The court finds that the agency has engaged in unlawful delay and orders the parties to mediate over a possible remedy.
 - **Feb. 2003** - In mediation, OSHA proposes to take over four more years to issue a final rule; Public Citizen proposes a two-year schedule. The mediator recommends a three-year schedule.
 - **March 2003** - The court accepts the mediator's proposed schedule, calling for issuance of the NPRM by October 2004, and a final rule by January 2006.
 - **Oct. 2004** - OSHA issues the NPRM on schedule. The proposal calls for a 50-fold reduction in the exposure standard for hexavalent chromium, although OSHA acknowledges that significant risks will remain at that level. OSHA's cited rationale for not lowering the standard further is a concern about the technological feasibility of a lower standard for only two industries, out of dozens, in which workers are exposed.
 - **Feb. 2005** - OSHA holds two weeks of hearings on the proposed rule. Public Citizen, the National Institute for Occupational Safety and Health (NIOSH), and labor groups testify that OSHA should reduce the exposure level still further to eliminate the significant risks that remain at the proposed exposure levels. Industry comes out in force to claim the proposed rule will be economically infeasible and to ask for a much more permissive standard.
 - **April 2005** - Industry groups present a new study to OSHA in post-hearing comments, claiming that it shows that low levels of exposure do not elevate cancer risks. Public Citizen points out that the study is underpowered to support any such conclusions.



Comments on
OMB's Proposed Bulletin
on "Good Guidance Practices"

January 9, 2006

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Citizens for Sensible Safeguards, a coalition of public interest groups which, together, represent millions of members nationwide, offers these comments in response to OMB's Nov. 30, 2005 notice in the *Federal Register*¹ inviting comments on OMB's Proposed Bulletin on "Good Guidance Practices."²

The public interest organizations working in partnership under the Citizens for Sensible Safeguards banner believe that the federal government has a vital role to play in protecting the public. "We, the people" create and use government institutions to accomplish shared goals. The unparalleled aggregation of resources that we have in our federal government entails a responsibility to use those resources to identify unmet needs and to act so that long-resolved problems do not erupt into new crises. FDR explained it best in one of the Fireside Chats: "It goes back to the basic idea of society and of the nation itself that people acting in a group can accomplish things which no individual acting alone could even hope to bring about."³ The federal government is a powerful way for the people to act on a national basis to meet national needs.

Accordingly, the organizations in Citizens for Sensible Safeguards understand that sound policy — whether workplace health and safety, environmental protection, consumer safety, income security, adequate investment in social services, or other public protections — requires public institutions that balance efficiency and process, participation and expertise, flexibility and accountability. We take an interest in any proposed government-wide policy that would upset that delicate balance, unduly burden the agencies charged with protecting the public, and prevent the federal government from meeting the public's needs.

OMB's Proposed Bulletin is the latest in a series of government-wide process changes that upset that balance, distorting government priorities and hindering the ability of federal agencies to fulfill their congressionally mandated duty to protect the public. Under the guise of well-meaning good government principles, OMB has aggressively pushed radical policies over the last five years that have undermined the very role of government itself. In the name of accountability, OMB published guidance on cost-benefit analysis that forces agencies to place the interests of industry above public needs, putting the most vulnerable at even greater risk. In the name of sound science, OMB has opened fire on established scientific research with its approach to implementation of the Data Quality Act. Now, in the name of public participation, OMB proffers the Proposed Bulletin on Good Guidance Practices, a seemingly innocuous measure that will only further ossify government by making the issuance of guidance as burdensome and draining on agency resources as the rulemaking process has become.

1. See Proposed Bulletin for Good Guidance Practices, 70 Fed. Reg. 71,866 (Nov. 30, 2005).

2. See OFFICE OF INFO. & REG. AFFS., OMB, PROPOSED BULLETIN FOR GOOD GUIDANCE PRACTICES (2005), available at <http://www.whitehouse.gov/omb/inforeg/regpol/good_guidance_preamble.pdf> (hereinafter "Proposed Bulletin").

3. See FDR, Fireside Chat, July 24, 1933.

We do agree that transparency and public participation are important goals. Accordingly, while we believe that there are better ways to achieve the goals of the public input and transparency requirements in § III of the Proposed Bulletin, we have no quarrel with the substance of that part of OMB's proposal. Our objections are instead focused on the unduly burdensome requirements in § IV of notice and comment for "economically significant" guidance documents, and we have some additional concerns about the potential for unnecessary politicization in the requirement of high-level review in § II.

Our comments have three major points to make:

1. The Proposed Bulletin is a solution in search of a problem. OMB claims that agencies are using general policy statements, handbooks, manuals, compliance guides, nonlegislative rules, and other informal matter as a vehicle for policy edicts that should go through the APA's notice-and-comment rulemaking process. Instead of taking the opportunity to improve the rulemaking process, OMB throws the baby out with the bathwater by adding new burdens to the production of information that the public needs.
2. The Proposed Bulletin is a roadmap for government that is less responsive to the public's needs. OMB would gain new power to intervene in day-to-day agency functions out of the public eye, while the public would also be left in the dark about agency policy. The Proposed Bulletin would force an unmanageably vast universe of distinct types of materials into a one-size-fits-all policy that, in the name of consistency, will threaten the consistency with which agency field offices implement government programs. The requirement that agencies subject guidance documents in high-profile issues to political review could result in the kind of inefficient bottleneck that is the hallmark of government mismanagement.
3. The Proposed Bulletin represents an unacceptable power grab by the White House. The principles and traditions of the American political order abhor the excessive centralization of authority that OMB would achieve with the Proposed Bulletin, which contravenes Congress's role in delegating responsibility and discretion to the agencies and assumes the right to amend the Administrative Procedure Act by executive fiat.

Finally, although we do not endorse the Proposed Bulletin and believe it is an inappropriate arrogation of power to the White House, we anticipate OMB's rejection of our arguments to set aside the Proposed Bulletin and offer, under protest, suggestions for reducing the risk of damage to public protections.

I. OMB'S PROPOSED BULLETIN IS A SOLUTION IN SEARCH OF A PROBLEM.

Agencies do not promulgate requirements for the sake of promulgating requirements. Government programs are purposive institutions created by democratically elected representatives and their agents to respond to the public's needs. When agencies use the authority granted to them by Congress to make decisions or create protective standards, they do so not for the abstract pleasure of exercising power but, rather, for the vital purpose of protecting the public.

The Proposed Bulletin is blind to the role of government in meeting the public's needs, and that blindness leaves OMB stumbling in the wrong policy directions. Starting with the questionable empirical claim that agencies are using guidance documents to announce requirements that should instead be legislative rules produced in accordance with the APA, OMB proceeds to an even more questionable response: clamping down on agencies' ability to develop guidance documents. Even if there is a problem with the impermissible use of guidance documents, the right solution should be to remove obstacles to the use of the regulatory process. Instead of making sure that government programs have the tools they need to serve the public, OMB has opted to make it increasingly difficult for agencies to do anything for the public.

Many of the organizations in Citizens for Sensible Safeguards have seen agency letters, preambles, handbooks, and other informal documents include assertions and policy changes that threaten public protections while avoiding the APA process.⁴ Likewise, we have seen corporate special interests challenge such materials as part of a sequence of efforts to slow agencies down from promulgating and enforcing regulations that cost them money to comply with. We do not have sufficient information — and OMB certainly has not provided it — to know whether there really is a widespread pattern in need of an across-the-board solution of the sort OMB proposes. Moreover, we do know that there are ways to pursue solutions to any such problem, which include advocating better practice from agency staff, litigating impermissible policy making, or asking Congress to legislate a targeted answer.

Even if OMB's unproven empirical claim were true, a pattern of agency efforts to avoid notice-and-comment rulemaking in favor of subterfuge rulemaking via guidance suggests a need for altogether different solutions than those proffered in the Proposed Bulletin. Instead of preventing agencies from giving the public the information or protective standards it needs, OMB should carefully examine the length of time it takes for an agency to finish a rule and whether the many additional analytical requirements that have accreted to the regulatory process — what law professor Peter Strauss calls the “tertium quid” of the regulatory process⁵ — constitute the real problem that needs to be addressed. Although a few analytical requirements call on agencies to ask themselves whether they are doing the

4. For example, as recently as December 13, 2005, the U.S. EPA issued guidance contravening the Clean Air Act, at industry's behest, that does not require consideration during the permitting process of whether a new power plant should use clean coal technology (known as integrated gasification combined cycle), instead of conventional coal-burning techniques. Such guidance will have the effect of undermining our clean air and contravenes Congress's intent under the new energy law to incentivize the use of such technology.

5. Peter L. Strauss, *The Rulemaking Continuum*, 41 DUKE L.J. 1463 (1992).

best they can for the environment or the most vulnerable members of the public, most proceed from the assumption that agency action is probably unwarranted and must be justified. The following is just a partial list:

- **E.O. 12,866:** By far the most onerous executive order, E.O. 12,866 requires agencies to determine if the rule is a “significant regulatory action,” meaning it has a significant impact on the economy or overall social cost of more than \$100 million or is otherwise deemed significant by the agency or OMB. If so, the agency must prepare Regulatory Impact Analysis (RIA), detailing the costs and benefits of the regulation.
- **E.O. 13,045:** If the rule is economically significant, the agency must also prepare an evaluation of the environmental health or safety effects of the proposed rule on children and explain why the proposed rule is preferable to alternatives under E.O. 13,045.
- **Congressional Review Act:** The Congressional Review Act mandates that rules that have a significant impact on the economy or impose costs of over \$100 million per year must be submitted to Congress with accompanying analysis before the rule can go into effect.
- **Unfunded Mandates Reform Act:** Agencies must also determine if the proposed rule will cause expenditures of more than \$100 million by state, local or tribal governments, or the private sector. If so, the agency must analyze the costs and benefits of the rule and identify alternatives to the rule that would impose fewer burdens.
- **E.O. 13,132:** As if UMRA does not require enough, E.O. 13,132 requires agencies to determine the federalism implications of a proposed rule. If the rule has federalism implications and either imposes significant direct compliance costs on states or preempts state law, the agency must prepare a “federalism summary impact statement,” including a summary of state and local officials’ concerns about the proposed rule and the agency’s position supporting the need for the regulation and a statement of the extent to which state and local concerns have been met.
- **Regulatory Flexibility Act:** Under the Regulatory Flexibility Act, agencies are required to determine if the rule will have a significant economic impact on a substantial number of small

entities. If so, the agency must prepare an initial Regulatory Flexibility Act analysis, detailing the impact of the rule on small entities, including an estimate of the number of small entities that will be affected, a description of information collection requirements on small entities, an explanation of measures taken to minimize burdens on small businesses, an explanation of why the rule was chosen and why alternatives were rejected. If the rulemaking does not impose a significant impact on a substantial number of small entities, the agency must certify and provide a factual basis for the conclusion.

- **Paperwork Reduction Act:** If the rule requires submissions of information by 10 or more persons, the agency must submit an information collection request including information necessary for OMB to determine if the information collection is necessary for the proper performance of the agency's function. If changes are made between the proposed and final rule, the agency may have to resubmit the information collection request before the final rule can take effect.
- **Trade Agreements Act of 1979:** Title IV of the Trade Agreements Act of 1979 requires agencies to determine if the rule sets a standard that creates an unnecessary obstacle to foreign commerce. If so, the agency may be required to use performance rather than design standards where appropriate. The agency must also consider and, where appropriate, use international standards.
- **E.O. 12,630:** If the proposed rule regulates private property for the protection of public health or safety, the agency must identify the public health and safety risk created by property use under E.O. 12,630. The agency must establish that the proposed rule substantially advances protecting the public from such risk and that the restrictions on property use are not disproportionate to the extent to which the property use contributes to the risk. The agency must also estimate the potential cost to the U.S. government if a court were to find the restriction a taking.
- **E.O. 13,211:** If rules have a significant energy impact, meaning the rule is a significant rule under E.O. 12,866 and is likely to have an adverse impact on the supply, use or distribution of energy or is otherwise considered to have a significant energy impact by OMB, then the agency is required to write an Energy Impact Statement, including an analysis of adverse

effects and any feasible alternatives, and submit the statement to OMB.

Some statutes also build in yet more analytical requirements specific to a particular area of regulatory activity, such as effluent controls.⁶

The evidence available suggests that these requirements have induced paralysis by analysis. As has repeatedly been observed, the average time from 1974 to 1992 for FTC final rules to reach finality after their initial proposal was 63 months.⁷ Likewise, the Occupational Safety and Health Administration has slowed significantly over the years as new burdens have been added:

[OSHA] in 1972 spent about six months from inception to publication of the final rule on its first occupational health standard for asbestos. Two of its next three health standards, a generic rule for fourteen carcinogens and a standards for vinyl chloride, took about one year, and nine months, respectively. The next three standards, for cotton dust, acrylonitrile, and arsenic, each took over three-and-one-half years. These last three standards were promulgated during the relatively activist Carter Administration when OSHA was anxious to write new rules to protect workers. Today, OSHA health standards rarely take less than five years to promulgate.⁸

This pattern is so widespread that it has given rise to an apt characterization of the regulatory process as "ossified."

6. See, e.g., Thomas O. McGarity, *Some Thoughts on "Deossifying" the Rulemaking Process*, 41 DUKE L.J. 1385 (1992):

[W]hen EPA promulgates regulations establishing national effluent limitations for industrial point source categories based on the "best conventional control technology," it must demonstrate that it has analyzed the cost of taking a unit of pollution out of an industrial effluent stream using the prescribed technology in comparison with the cost of removing an equivalent unit of pollution from a municipal sewage treatment works. The agency must also compare the incremental cost of the prescribed technology with the incremental cost of installing somewhat less stringent "best practicable control technology." It must also analyze the age of equipment and facilities involved, the process employed, the engineering aspects of the application of various types of control techniques, process changes, and the non-water quality environmental impact (including energy requirements)

Id. at 1403-04.

7. *Id.* at 1389 n.22.

8. *Id.* at 1387-88.

We need government programs to be able to act on behalf of the public. The unparalleled aggregation of resources that we have in our federal government entails a responsibility to use those resources to identify our unmet needs and to act so that long-resolved problems do not erupt into new crises. OMB has already burdened the regulatory process so that agencies cannot quickly respond to the public's need for protective standards. If there is a problem with agencies failing to use the regulatory process, it is the fruit of OMB's own aggressive policies that undermine the role of government. OMB should offer solutions that make government agencies better equipped to address the public's needs, not less able to provide information to the public.

II. OMB'S PROPOSED BULLETIN WILL MAKE GOVERNMENT LESS EFFECTIVE AT SERVING THE PUBLIC'S NEEDS.

As usual, OMB masks the risks of its latest government-wide proposal with good government principles. OMB offers the Proposed Bulletin as a solution for its concern that "agency guidance practices should be more transparent, consistent, and accountable."⁹ Such concerns, as well as the public's right to participate in important decisions, are important concerns that we all share. These concerns do not, however, exist without a context. The bottom line for questions of government management is not management itself but, rather, meeting the public's needs. However much we talk about good government, a government that is not responsive to the public's needs is not good enough.

The Proposed Bulletin is a roadmap for mismanagement of government. Despite touting transparency, consistency, and accountability, the Proposed Bulletin poorly serves the good government goals it claims to achieve. Instead, OMB's Proposed Bulletin will make government less transparent, impose the wrong kind of consistency at the expense of a consistency that the public needs, and burden the agencies' achievement of the very responsibilities for which they should be held accountable.

A. The Proposed Bulletin will apply a crude one-size-fits-all policy to an unmanageably immense universe of materials.

No one is opposed to "consistency" *qua* consistency. Nonetheless, consistency alone cannot justify a wide-ranging government process change unless it will create a needed consistency that improves the government's ability to protect the public. The problem with the Proposed Bulletin is that it does not justify the kind of consistency it intends to impose while robbing the public of a kind of consistency it has come to expect with guidance documents.

The Proposed Bulletin's definition of affected guidance documents notionally limits the scope of the Proposed Bulletin while actually applying new burdens to an immense universe of agency materials. OMB's Proposed Bulletin defines the materials subject to the new "good guidance practices" requirements as

9. Proposed Bulletin, *supra* note 2, at 2.

- (1) a document produced by an agency other than an independent agency
- (2) that is public or subject to the Freedom of Information Act
- (3) and is neither a rulemaking or an adjudication,
- (4) that describes an agency's
- (5) *interpretation of or policy on*
- (6) *a regulatory or technical issue*
- (7) and *may*
 - (a) raise "highly controversial issues,"
 - (b) implicate "important" Bush administration priorities,
 - (c) provide initial interpretations of statutory or regulatory requirements,
 - (d) announce changes in previous interpretations or policies,
 - (e) address "novel or complex *scientific* . . . issues,"
 - (f) address "novel or complex . . . *technical* issues," or
 - (g) be "economically significant" by being reasonably anticipated to
 - (i) "lead to an annual effect of \$100 million or more" or
 - (ii) "adversely affect in a material way the economy or a sector of the economy."¹⁰

The term "guidance documents" would suggest a focus on materials like compliance guides, but this definition is incredibly capacious, sweeping in an immense universe of diverse materials, the sheer volume of which would overwhelm agencies forced to apply these new requirements. The definitions of "significant guidance documents" and "economically significant guidance documents" are so broad that they could result in any or all of the following scenarios:

- The Department of Labor is called upon frequently to offer guidance to workers and employers. Between 1996 and 1999, DOL "issued 3,374 guidelines, manuals, policy statements, handbooks and such that qualified as guidance."¹¹ Any subset of that output would still be substantial. For example, between 2001

10. *Id.* § I at 9 (emphasis added).

11. Cindy Skrzycki, *Finding a Way to Better Guidance*, WASH. POST, Dec. 20, 2005, at D1.

and 2005, OSHA issued 574 standard interpretations, 300 of which interpreted standards for the construction industry alone. Recent standard interpretations address, *inter alia*, employees' rights upon termination to access to a physician's written opinion and respirator fit test results, whether DOT's labeling requirements for shipments of biohazardous materials suffice in lieu of OSHA's requirements, the requirement that respirator breathing air cylinders must be maintained in a fully charged state, and engineering controls for removal of asbestos-containing construction mastic.

- The Department of Labor's Wage and Hour Division is often called upon to "respond to public inquiry about application of the wage and hour laws" — responses that, in the 1970s, averaged "roughly 750,000 letters each year," none of which are "in themselves binding on the public" but merely "indicate circumstances in which the Division might seek a judicial remedy."¹² An early federal court case determining the standard of review for such letters decided that only the approximately 10,000 of those letters then signed yearly by the administrator would constitute final agency action ripe for APA review, adding that "advisory opinions should, to the greatest extent possible, be available to the public as a matter of routine."¹³ Because such letters are interpretations of statutory and regulatory requirements that could, for firms that decide to comply with the advice, generate costs in the \$100 million range, they could be subject to exactly the kinds of burdensome requirements that the early court decision wisely declined to incentivize.
- EPA's Risk Screening Environmental Indicators model integrates hazard and exposure data to rank sources of toxic chemical releases.¹⁴ The ranking of toxic chemical

12. Strauss, *supra* note 5, at 1486.

13. *Id.* at 1486-87 (quoting *National Automatic Laundry & Cleaning Council v. Schultz*, 443 F.2d 689, 697 (D.C. Cir. 1971)).

14. See EPA, Risk Screening Environmental Indicators, available at <http://www.epa.gov/opptintr/env_ind/index.html>; see also Ken Weinstein, *Committee Co-Sponsors 9th Section Fall Meeting Panel: Rules Versus Guidance*, available at

release sources could constitute an interpretation of a technical issue that is “controversial,” a “novel or complex scientific . . . issue[],” or a conclusion reasonably anticipated to “adversely affect in a material way” the companies responsible for the toxic releases. The Proposed Bulletin could require EPA to justify its rankings in response to comments filed by the worst polluters.

- The IRIS database, which contains risk information on the effect of toxic chemicals on human health, guides industries on the safe level of exposure to a variety of chemicals. Subjecting this controversial data to peer review and notice-and-comment could cripple the ability of EPA to release this important information on the adverse human health effects of a variety of chemicals. The state, local and federal governments often rely on IRIS data to set regulated exposure limits. Opening up IRIS data to notice and comment could, thus, hinder federal and state agencies from setting appropriate exposure limits.
- The Superfund program relies extensively on guidance documents to carry out the work of cleaning up contaminated sites. The guidance documents give instructions on how to assess and clean up the sites as well as provide important information to the public on the risks of the contaminated area. Relying on notice-and-comment for such a large universe of guidance documents would substantially hamper an already sluggish cleanup program.
- EPA recently introduced the “Arsenic Virtual Trade Show” website (<http://www.arsenictradeshow.org/>), which gives water utility companies compliance guidance on removing arsenic from drinking water. The website is able to give the regulated industry the latest information on the most cost-effective and efficient means for removing arsenic. If EPA were forced to go through a notice-and-comment period in order to tell industry about better means of compliance, both members of the regulated community and the general public would lose out.

- The FAA alone “generates approximately 215 feet of domestic and international notices yearly”;¹⁵ if even a fraction of that output were subject to the Proposed Bulletin’s notice-and-comment process, the FAA would end up diverting substantial resources away from ensuring safety for air travel.
- The National Weather Service not only reports on weather and air conditions but also gives consumers guidance on the best course of action to take in severe weather conditions. NWS heat advisories, for instance, advise the public, especially the young and elderly, when to stay indoors because of severe heat. Instructing individuals to stay indoors potentially has a significant economic impact on businesses, but subjecting heat advisories to a notice-and-comment period would be an absurd and potentially dangerous burden on the NWS with potentially hazardous results for the public.
- U.S. Customs Service ruling letters setting tariff classifications for particular imports, such as determining whether Mead day planners should be classified as bound diaries subject to tariff or in a duty-free class of “[r]egisters, account books, notebooks, order books, receipt books, letter pads, memorandum pads, diaries and similar articles,¹⁶ would constitute an initial or changed interpretation of statutory and/or regulatory requirements that, in some cases, could result in a company bearing the cost of import tariffs which, combined with the downward pressure on profits and indirect economic effects, could in the hands of an enterprising economic analyst be found to reach \$100 million or more. There are 49 different customs offices that, when the Supreme Court reviewed the *Mead* case, issued 10,000 to 15,000 such classifications. These ruling letters could conceivably be subject to full notice and comment.
- The USDA issues notifications to the general public on food preparation, such as advisories that meat and poultry products should be cooked until they reach

15. Strauss, *supra* note 5, at 1469 n.20.

16. United States v. Mead Corp., 533 U.S. 218, 224 (2001).

specific internal temperatures. If USDA were to update its assessment of doneness temperatures, there could be economic consequences for restaurateurs, cookbook publishers, and manufacturers of meat thermometers. Conducting notice and comment on such changes could make the USDA docket website rival *Gourmet* magazine's web message boards.¹⁷

The distinct kinds of materials and heterogeneous subject matters that could come within the Proposed Bulletin's reach serve a wide range of public needs and are so diverse that a one-size-fits-all policy like the Proposed Bulletin poses a serious risk of causing more problems than it solves.

OMB has given us reason to believe these risks are significant. Although OMB purportedly based its proposal on existing Food and Drug Administration regulations on guidance practices, it is interesting to note that FDA's regulations expressly exclude changes "that are of more than a minor nature."¹⁸ FDA also expressly rejected ACUS Recommendation 76-5 when it devised its good guidance policy, stating that it would invite litigation and require agencies to respond to matters of limited public interest.¹⁹ It is quite likely that other agencies, which know their issues far better than OMB ever could and thus are far better positioned to evaluate the public's need for timely information, would respond similarly. OMB's one-size-fits-all edict does not give them that chance and ignores FDA's counsel that such a policy is overbroad.

Even assuming that OMB means for the Proposed Bulletin only to apply to compliance guides and other such explanatory materials traditionally referred to as "guidance documents," the Proposed Bulletin threatens to burden the production of valuable information. Agencies often explain how they intend to administer a statute or regulation through interpretive rules²⁰ and general policy statements that state an agency's tentative but not binding intentions for the future.²¹ These explanations can provide structure to an agency's enforcement activities,²² which in turn can create consistency in enforcement patterns across an agency's regional and program offices and offer the regulated public more clarity:

The whole point of the exercise is to structure discretion, to provide warning and context for efficient interaction between the agency and

17. Available at <<http://www.epicurious.com/forums/>>.

18. See 21 C.F.R. § 10.115(c)(ii).

19. See 61 Fed. Reg. 9181, 9183 (Mar. 7, 1996).

20. See, e.g., *McCown v. Sec'y of Health & Hum. Servs.*, 796 F.2d 151, 157 (6th Cir. 1986); *New Jersey v. Dep't of Health & Hum. Servs.*, 670 F.2d 1262, 1281-82 (3d Cir. 1981).

21. See, e.g., *American Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1046 (D.C. Cir. 1987).

22. See *Erringer v. Thompson*, 371 F.3d 625, 633 n.15 (9th Cir. 2004).

the affected public. This is the plain implication of the rationale for [the kinds of materials that the Proposed Bulletin would govern] — and, for that matter, the negative pregnant of section 552(a)(2), forbidding the citation of [them] “against a party other than an agency” unless they have been properly published and indexed.²³

Even as priorities change from administration to administration, guidance documents can ensure that each incoming administration’s approach to technical and policy issues is consistently applied on a fair basis nationwide, so that no member of the public is prejudiced by living in a jurisdiction covered by a field or regional office with either more stringent or less protective inclinations. This kind of consistency is particularly important for *federal* government programs, which are charged with providing national solutions for national needs.

By creating this new one-size-fits-all approach to “guidance documents” across the entirety of the federal government, OMB’s Proposed Bulletin threatens to create disincentives to the production of the guidance materials that ensure this kind of valuable consistency. “Requiring internal procedures as the cost of giving advice or creating structure is a cost imposed in every case . . . Careful attention needs to be paid to the costs of ‘mak[ing] an agency reluctant to give [such notice of its views].’”²⁴ OMB does not appear to have thought through this trade-off.

B. The Proposed Bulletin will leave the public in the dark.

Another ill-conceived trade-off in the Proposed Bulletin is that its supposed transparency gains come at the cost of valuable information the public needs. One consequence of the “structured discretion” discussed above is that the public can have advance notice of an agency’s approach to implementing its programs, long before an agency has to issue a warning letter to a Medicaid provider or impose a fine on a polluting company. The requirements of notice and comment and subjecting all guidance documents for approval by political appointees will delay the release of guidance and could create such heavy burdens that agencies will decline to produce the guidance at all.

Such has been the case in California, which has applied its Administrative Procedure Act and a variety of analytical requirements (including a parallel of OMB review) to nonlegislative rules and guidance documents.²⁵ Even though agencies are “often required to respond quickly to demands for guidance — for example, from a new court decision or a new statute or an emerging problem,” agencies cannot provide guidance until the entire burdensome process has concluded.²⁶ Because of the significant costs and delays, California agencies emphasize case-by-case adjudication instead of

23. Strauss, *supra* note 5, at 1486.

24. *Id.* at 1487 (quoting Schultz, 443 F.2d at 700 (emendations in original)).

25. See generally Michael Asimow, *California Underground Regulation*, 44 ADMIN. L. REV. 43 (1992).

26. *Id.* at 56.

simple prophylactic guidance to reveal their intentions.²⁷ They often avoid written materials to structure field staff decision making, relying instead on oral presentations at training sessions.²⁸ Just as likely is that the agencies produce no guidance at all, “thus shifting the burden of uncertainty onto the public.”²⁹

Meanwhile, OMB is setting itself up for a powerful new role in day-to-day agency affairs that will presumably take place entirely out of the public eye. The Proposed Bulletin requires agencies to consult with OMB before excluding any specific documents or classes of guidance documents from the notice-and-comment process expected of “economically significant” guidance documents. This consultation in case-by-case decisions of the Proposed Bulletin’s applicability will give meaning to the Proposed Bulletin that the definitions of the Proposed Bulletin itself fail to provide, but the public will not have access to those backdoor decisions.

C. The Proposed Bulletin uses accountability as an excuse to undermine agency responsibility to protect the public.

Accountability means helping the people maintain control over their own government so that programs and services can continue to meet the public’s long-term and emerging needs. Accountability should not, however, be the excuse for policies that so burden the public’s agents that they cannot address the public’s unmet needs. Given the risk that policies instituted in the name of accountability could come with costs that keep government from being responsive, it is important for any major accountability initiatives to build in reflexivity: checks that count the costs of accountability reforms, assess the performance of performance measurement rubrics, and make sure that reforms are not obstacles in the way of responsive government.

OMB has failed to create accountability controls for the Proposed Bulletin. As we explain above, the Proposed Bulletin will come with opportunity costs and measurable costs in staff time lost and public benefits unduly delayed. Given the high stakes involved, it is noteworthy that OMB has not applied to the Proposed Bulletin the same controls it insists are needed in routine government functioning. Although OMB has promoted the concept of mandatory “sunsets” or expiration dates

27. *Id.* at 58. This very scenario is, in fact, part of the rationale for the APA’s exemption of interpretations and other informal matter from notice and comment. *Accord see* American Mining Cong. v. Mine Safety & Health Admin., 995 F.2d 1106, 1111-12 (D.C. Cir. 1993) (cautioning that agencies’ “ability to promulgate [interpretive] rules, without notice and comment, does not appear more hazardous to affected parties than the likely alternative. Where a statute or legislative rule has created a legal basis for enforcement, an agency can simply let its interpretation evolve ad hoc in the process of enforcement or other applications (e.g., grants). The protection that Congress sought to secure by requiring notice and comment for legislative rules is not advanced by reading the exemption for ‘interpretive rule’ so narrowly as to drive agencies into pure ad hocery—an ad hocery, moreover, that affords less notice, or less convenient notice, to affected parties.”).

28. Asimow, *supra* note 25, at 58.

29. *Id.* at 59.

of all government programs,³⁰ OMB does not recommend any sunset of the Proposed Bulletin and its onerous requirements. OMB has zealously moved to assess the performance of government programs to measure their effectiveness³¹ and ordered agencies to compare the costs and benefits of proposed regulations, while the Proposed Bulletin presumes its own effectiveness and builds in no safeguards to assess whether its purported benefits justify the costs. This inconsistency only resolves into coherence when we consider the shortcomings we identify above in section I of these comments: that OMB's Proposed Bulletin is another attack on the positive role of government.

Additionally, although it is not completely clear on the face of the Proposed Bulletin, we are concerned by the possibility that § II(1)(b) could create a political bottleneck in the agencies that could slow down or even politicize the issuance of guidance. The requirement that all "significant" guidance documents be submitted to "senior agency officials" for approval could distort an entire political economy of accountability of actors and significance of action that the informality of guidance documents helps to establish:

[Notice-and-comment] rulemaking is both a less frequent and a more highly centralized form of rulemaking than is [the publication of informal guidance]. The relationship between these two forms of activity mirrors, within the agency, the relationship between legislation and rulemaking in the larger governmental context. One can imagine a framework of ever-increasing specificity, in which increasing detail is provided by procedures of diminishing rigorousness, adopted by actors of diminishing responsibility. At the apex lies the Constitution Legislation is more specific, adopted [by elected representatives]. Yet we accept that, in a complex society, [Congress may pass nothing more than] large frameworks for the resolution of issues, leaving their actual resolution in detail to agencies . . . whose political accountability is secured by appointment mechanisms and the possibility of presidential and/or congressional oversight. And the agencies in turn find that complex subjects, required procedures, and the twenty-four-hour day limit the capacities of those at the very top of the agency to deal with their responsibilities; ideally, those at the head take the most important of decisions, creating an internal framework or structure of essential judgments, and then leave the inevitable further details to be worked out by their more numerous and

30. See OMB Watch, *White House Demands Power to Restructure Government*, OMB WATCHER, July 11, 2005, available at <<http://www.ombwatch.org/article/articleview/2916/1/330?TopicID=1>>. For more, consult recent OMB Watch testimony on House bills that would implement the White House proposal, available at <<http://www.ombwatch.org/regs/2005/testimonyresunsetresults.pdf>>.

31. For background and analysis on the White House's performance measurement rubric, the Program Assessment Rating Tool, see Adam Hughes & J. Robert Shull, OMB Watch, *PART Backgrounder*, available at <<http://www.ombwatch.org/regs/2005/performance/PARTbackgrounder.pdf>>.

expert staff—subject to techniques of control and oversight far more likely to be bureaucratic and procedural than directly political.³²

The role of guidance documents in this scheme is to serve as “a means for supplying additional detail unreasonable to expect at the level of the agency head, and in a form sufficiently flexible to permit relatively fast and easy change.”³³

The nomenclature OMB has chosen to use in the Proposed Bulletin makes it difficult to predict in advance what really is at stake in § II(1)(b) of the Proposed Bulletin. A “guidance document” is almost any interpretation of a regulatory issue, interpretation of a technical issue, policy on a regulatory issue, or policy on a technical issue; “significant” ones are those that *may* meet elements (7)(a)-(g) that we summarized above,³⁴ none of which necessarily weeds out routine interpretations and the like for which there is little public value in requiring high-level review but great public value in the timely issuance of such information. Given the immense universe of materials covered by the Proposed Bulletin and the agencies’ greater expertise in the issues at stake and the public’s relative need for quick publication, it seems prudent for OMB to eliminate this section and allow the agencies to continue making their own decisions about materials that require high-level review, so that a one-size-fits-all policy does not create the risk of a bureaucratic bottleneck preventing the public from receiving the information it needs in a timely manner.

Moreover, agency guidance documents do not escape accountability when they stray from guidance to illegal rulemaking. As we explain below,³⁵ there are distinct outer boundaries to agencies’ discretion in producing guidance, general policy statements, and non-legislative rules. Further, the agencies always remain accountable to Congress, which has the power to limit and expand the agencies’ discretion as cases for such changes arise. Instead of creating for itself yet another powerful backdoor role in distorting policy and weakening protective standards for which it is not accountable to anyone, OMB should set aside the Proposed Bulletin on guidance and instead address the problem of paralysis by analysis that prevents agencies from meeting the public’s needs.

III. OMB’S PROPOSED BULLETIN IS AN UNACCEPTABLE POWER GRAB.

Even the best of goals can be achieved in the worst of ways. Such is the case with OMB’s Proposed Bulletin. Assuming *arguendo* that there is a problem with agencies using guidance documents to impose obligations on the public without being accountable to the public, it is wrong for OMB to legislate by executive fiat and to use the problem as an occasion to arrogate power that Congress has chosen to delegate directly to the agencies and not the White House.

32. Strauss, *supra* note 5, at 1476-77.

33. *Id.* at 1478.

34. See text accompanying note 9 *supra*.

35. See text accompanying notes 38-42 *infra*.

OMB's Proposed Bulletin reverses important decisions about administrative law and government management that are now backed with 60 years of precedent. Congress already spoke to the balance of efficiency and process in the Administrative Procedure Act itself, which exempts "interpretative rules, general statements of policy, [and] rules of agency organization, procedure, or practice" from the notice and comment requirements applied to legislative rules.³⁶ The rationale is that agencies should have the flexibility to announce their intentions for the future, clarify how they will apply or enforce a statute or regulation, and create consistency across field offices in the day-to-day implementation of their work. In exchange for that flexibility, agencies essentially lose the power to bind the public to those decisions (although they can sometimes bind themselves), and reviewing courts will apply not *Chevron* deference but, instead, the lesser degree of respect called for in *Skidmore*.³⁷ When agencies do need to bind the public with a legislative rule, the stakes for the public are higher, and so they have to go through the APA process but are rewarded with court deference to their decisions.

Moreover, these guidance documents are not published in some completely lawless zone. Interpretive rules cannot be inconsistent with prior legislative rules, else they run the risk of not being applied.³⁸ They cannot create the substantive requirements that legislative rules can, else they can be rejected as having failed to comply with the APA.³⁹ Even when they stop short of being complete rules, informal materials that purport to create exceptions to otherwise permissible rules can be tossed aside.⁴⁰ In fact, even the flexibility inherent in such documents may have its limits, as courts could reject interpretive rules that are abrupt departures from longstanding practice.⁴¹ Finally, the Freedom

36. See 5 U.S.C. § 553(b)(A).

37. See, e.g., *National Railroad Passenger Corp. v. Morgan*, 536 U.S. 101, 111 n.6 (2002) (declining to defer to Equal Employment Opportunity Commission's Compliance Manual interpretation of what constitutes continuing violations for purposes of determining timely filing); *United States v. Mead*, 533 U.S. at 231-34 (declining to accord *Chevron* deference to U.S. Customs Service ruling letters setting tariff classifications for particular imports); *Christensen v. Harris County*, 529 U.S. 576, 587 (2000) ("Here, . . . we confront an interpretation contained in an opinion letter, not one arrived after . . . notice-and-comment rulemaking. Interpretations such as those in opinion letters — like interpretations contained in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law — do not warrant *Chevron*-style deference. Instead, [they] are entitled to respect under our decision in *Skidmore*[,] but only to the extent that [they] have the power to persuade.") (citations and quotation marks omitted); *EEOC v. Arabian American Oil Co.*, 499 U.S. 244, 257 (1991) (declining to apply *Chevron* deference to EEOC interpretive guidelines); *Martin v. Occupational Safety & Health Rev. Comm'n*, 499 U.S. 144, 157 (1991) (holding that interpretative rules and enforcement guidelines are "not entitled to the same deference as norms that derive from the exercise of the Secretary's delegated lawmaking powers").

38. See *Hemp Industries Ass'n v. DEA*, 333 F.3d 1082, 1088 (9th Cir. 2003); *Columbus Community Hosp. v. Califano*, 614 F.2d 181, 187 (8th Cir. 1980).

39. See, e.g., *South Dakota v. Ubbelohde*, 330 F.3d 1014, 1029-30 (8th Cir. 2003).

40. See, e.g., *Mt. Diablo Hosp. Dist. v. Bowen*, 860 F.2d 951, 957-59 (9th Cir. 1988).

41. See, e.g., *Shell Offshore, Inc. v. Babbitt*, 238 F.3d 622, 630 (5th Cir. 2001).

of Information Act already insists that the materials exempted from notice-and-comment rulemaking must be made public and limits their availability as precedent in enforcement actions.⁴²

Congress has not empowered OMB to upset this delicate balance. Congress retains that power, and it has made targeted changes to this basic framework for specific cases over the years. For example, as OMB repeatedly observes, Congress waived this general exception for the Food and Drug Administration and essentially codified that agency's guidance practices.⁴³ In other cases, Congress has specifically empowered the agencies to make significant decisions, such as approving or rejecting state plans to implement cooperative federalism programs, without having to go through the APA process. Congress has had 60 years to consider across-the-board, one-size-fits-all policies of the type OMB is proposing, and it has opted to leave in place the current general scheme.

In the absence of any such direct intervention, Congress has left these matters up to the agencies to exercise their discretion. In fact, several agencies that implement public grants and benefits programs voluntarily waive the APA exemption for many of their important but otherwise exempt decisions. Some agencies already have guidance practices of their own for compliance guides, handbooks, and the like, and many have quality controls or other policies in place to govern the publication of many of the other kinds of informational materials that could conceivably be covered by the Proposed Bulletin. This mix of express and implicit delegations to the agencies means, among other things, that the agencies (which know their issues with more breadth and depth than any generalist in OMB) can develop policies appropriate for the specific kinds of information and public needs at stake in the many "guidance documents" the agencies produce.

Our concern in this regard is partly one of principle. Unless Congress legislates to the contrary, the president lacks the "authority to dictate decisions entrusted by statute to executive officers."⁴⁴ It is deeply problematic for OMB to interfere with Congress's decisions to delegate discretion to the agencies, particularly in the form of a proposal that seeks to advance good government. It is even more troubling that OMB is attempting to amend the APA by executive fiat. Any guidance documents — which would include interpretive rules, general policy statements, and more — that fall into the "economically significant" category would be subject to exactly the kind of notice-and-comment process hurdles from which Congress decided to exempt them. The sixtieth anniversary of the APA may be an occasion to consider how the law is working and even how it can be improved, but it is not time to rewrite the law unconstitutionally by executive pronouncement.

Although OMB does not arrogate to itself the power to review agency guidance documents before they can be published, OMB is nonetheless writing itself a significant and inappropriate role in day-to-day agency functioning. The Proposed Bulletin purports to offer agencies some flexibility in implementing the rigid notice and comment requirement for "economically significant" guidance

42. See 5 U.S.C. § 552(a)(1)-(2).

43. See, e.g., Food and Drug Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296, 2396 § 405 (codifying FDA guidance practices to regulate production of informal agency statements).

44. Robert V. Percival, *Presidential Management of the Administrative State: The Not-So-Unitary Executive*, 51 DUKE L.J. 963, 966 (2001).

documents, but that flexibility comes with a price: agencies can only exempt specific documents or classes of documents “in consultation with” OMB.⁴⁵ As we discuss below, the Proposed Bulletin will apply to a vast universe of materials and will almost immediately run into potential legal difficulties, so there will be need for much OMB “consultation.” The day-to-day implementation of the Proposed Bulletin and its exemption clause will create many new opportunities for White House interventions in the agencies’ work to protect the public.

More importantly, though, our concern is the effect on the public’s ability to receive the information it needs. The Proposed Bulletin’s interference in matters trusted by Congress to agency discretion concerns us because OMB knows far less than the agencies about what’s at stake in the immense universe of materials governed by the Proposed Bulletin. As we have discussed above, we fear that the Proposed Bulletin, in particular § IV, will create unnecessary burdens on the publication and release of information that the public needs. We believe that the agencies are in a far better position than the generalists at OMB to exercise the discretion on issues of non-rulemaking materials with which Congress has entrusted them. The enormous risk of information delays and gaps that we have discussed above does not inspire confidence that the Proposed Bulletin will do a better job than the agencies currently do.

IV. OMB MUST, AT A MINIMUM, TAKE STEPS TO MINIMIZE THE DAMAGE FROM THE PROPOSED BULLETIN.

We reiterate our position that the Proposed Bulletin is largely a solution in search of a problem and an overreach of OMB’s authority, but we realize that OMB is planning to forge ahead with this initiative. The best recommendation is for OMB to stop altogether, but we also offer, under protest, recommendations for narrowing the scope of damage that the Proposed Bulletin portends.

- The most troubling part of the Proposed Bulletin is the notice-and-comment requirement for “economically significant” guidance. Not only is the term “economically significant guidance” misleading and incomprehensible, but the added burden on agencies for guidance documents that fall under this domain would be onerous and draining on agency resources. Guidance documents are specifically exempt from APA notice-and-comment, and subjecting them to such procedures is an overreach of executive power. We propose that OMB eliminate APA-style notice-and-comment for “economically significant” or any other class of guidance documents.
- OMB should further clarify its vague and ambiguous definitions for various types of guidance documents.

45. Proposed Bulletin, *supra* note 2, § IV(2) at 11.

We suggest that OMB vastly limit the scope of guidance documents requiring formal notice and comment so as not to grind agency activity to a complete halt. Certainly, unnecessarily draining agency resources is not OMB's objective.

- The Proposed Bulletin gives OMB the authority to waive agency compliance with the bulletin for specific guidance documents. In the interest of transparency, we believe that any criteria OMB uses to approve or deny the waiver as well as any rationale provided by the agency for waiving the good guidance practice requirements should be made public on the OMB website. Ideally, OMB would maintain an online docket similar to the current docket that charts OMB's regulatory reviews under E.O. 12,866, but this docket should offer much more detail about OMB's instructions or "consultations."
- Though the Proposed Bulletin thankfully did not include analytical burdens on guidance documents, we would like to stress that these burdens, particularly cost-benefit analysis, should not be applied to guidance documents.
- The Proposed Bulletin was released immediately prior to Thanksgiving, and the comment period included major religious holidays. Given the short time the public has been given to review OMB's Proposed Bulletin, we request that OMB submit another draft for public comment and encourage OMB to confer with Congress in a broadly bipartisan manner. Considering the range of concerns that have been raised by us as well as those inside the agencies, we believe this issue requires further analysis and public discussion before OMB makes a final decision. Although OMB undoubtedly would like to finish its decision in time to observe outgoing OMB-OIRA administrator John Graham's exit from OMB on Feb. 1, we think that the issues raised by the Proposed Bulletin are too important to rush.
- Finally, we believe it is long past time for OMB or a nonpolitical office such as GAO to analyze the burden and opportunity costs attendant to the ossification of

the regulatory process, including time spent complying
with the Proposed Bulletin.

Respectfully submitted,

Sheila Crowley
President
National Low Income Housing Coalition

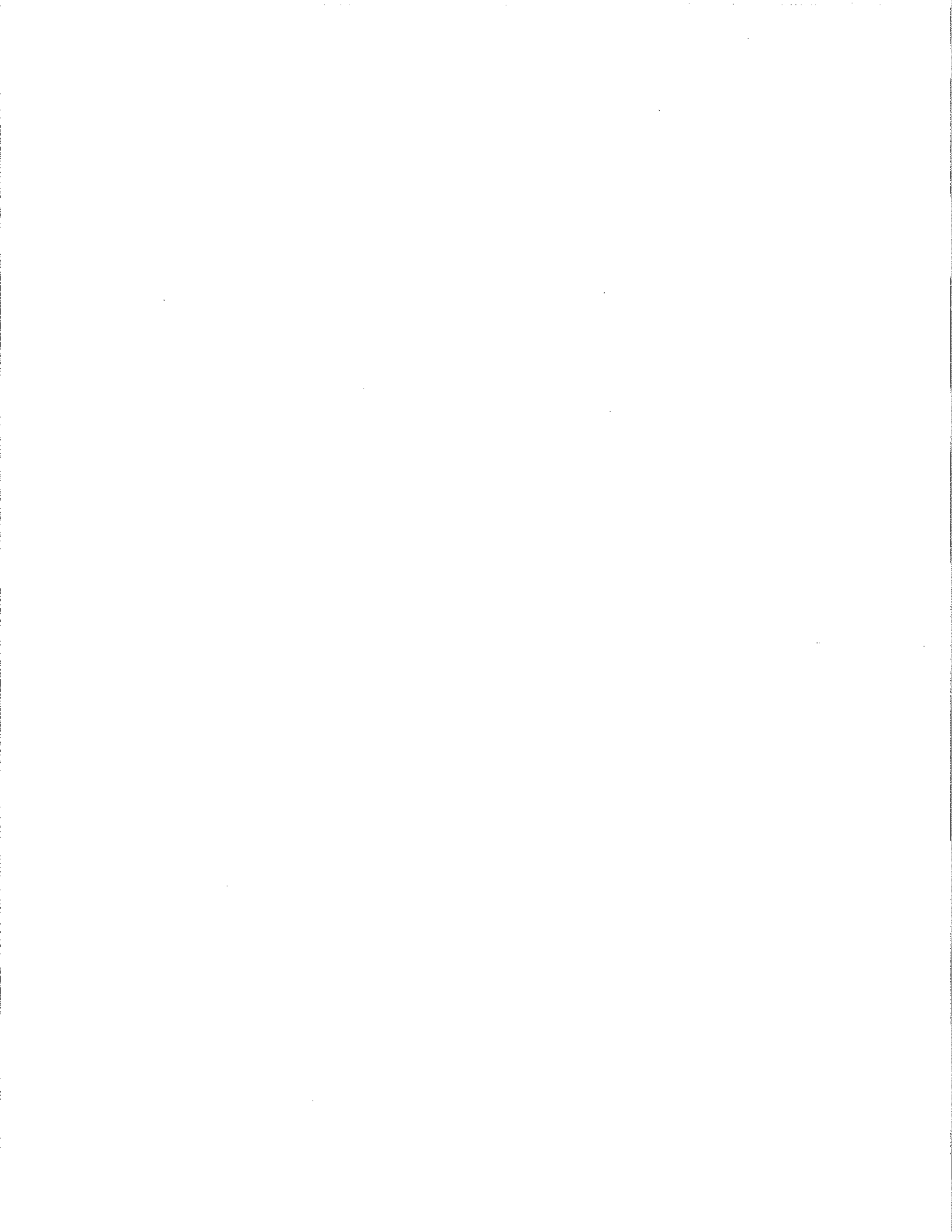
Robert Greenstein
Executive Director
Center on Budget and Policy Priorities

Charles M. Loveless
Director of Legislation
American Federation of State, County & Municipal Employees (AFSCME)

Laura MacCleery
Deputy Director, Auto Safety Group
Public Citizen

Peg Seminario
Safety and Health Director
AFL-CIO

J. Robert Shull
Director of Regulatory Policy
OMB Watch





FROM GUIDANCE TO DARKNESS

How Bootstrapping Exec. Order 13,422 & "Good Guidance" Bulletin Threatens Risk Assessment

OMB's new memorandum on risk assessment spends several pages saying very little — until the last page, when it declares that OMB's policy for "good guidance practices" (Exec. Order No. 13,422 and accompanying Final Bulletin on Agency Good Guidance Practices) governs risk assessments. By bootstrapping the guidance policies onto the risk assessment memo, OMB has now declared open season on any controversial scientific assessment that industry has an interest in opposing.

Blink and You'll Miss It

One strategically buried sentence: "Agencies should refer to OMB's Final Bulletin for Agency Good Guidance Practices . . . for updated guidance regarding best practices for increasing public access and public comment concerning guidance documents and influential scientific information" (Memo at 13).

How It Works

Any risk assessment that is "significant" because it "may reasonably be anticipated to" —

1. Lead to an annual effect of \$100 million or more
2. Adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or [state/local/tribal government]
3. Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency
4. Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights or obligations of recipients thereof
5. Raise novel legal or policy issues....

Will now be subject to the following new delays and political hoops:

Increased political review

- Review and approval by senior agency official (GGP Bull. § II(1)(a))
- And review and approval by OMB's regulatory office, OIRA (EO § 7)

Time-wasting challenges by industry

- Open to challenge under *two* processes
 - Data Quality Act *and*
 - System for comment and challenge created by GGP Bull. § III
- If *economically* significant (factors #1-2 to the left): notice in *Federal Register* and opened to comment, followed by response-to-comments document (GGP Bull. § IV(1))

What It Means

Delay The National Research Council observed, "Many risk assessments take considerable time, some several years." Noting that "[t]ime, like funds in the federal government, is a limited commodity," the NRC rejected OMB's earlier draft risk assessment bulletin, concluding *inter alia* that it would result in "fewer risk assessments (with the attendant consequences) or the same number of risk assessments but of lower quality." By importing the laborious "good guidance practices" into standards for risk assessment, OMB has simply found another path to the same problems.

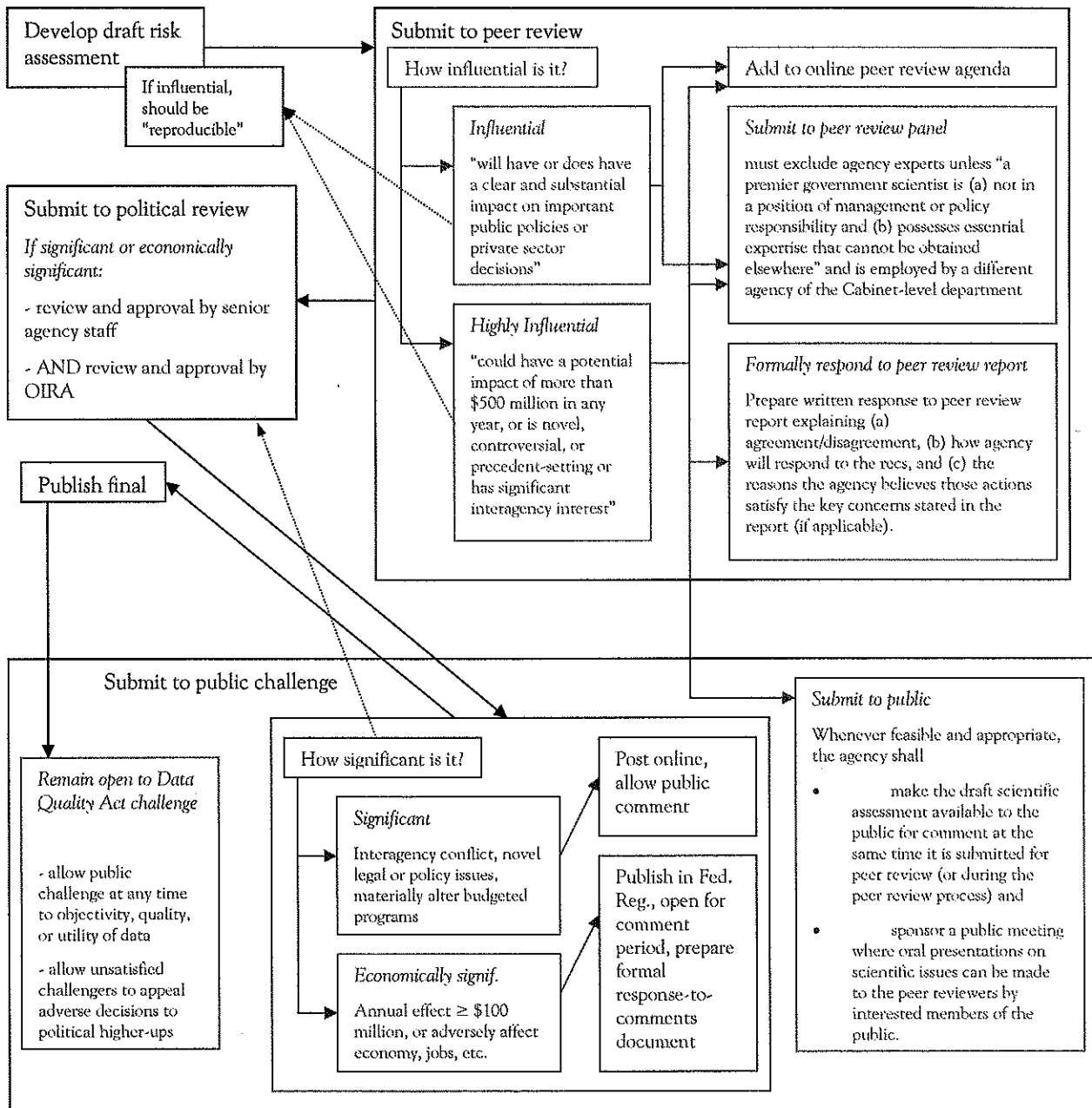
Politics over science Double the challenge by industry, double the review by political higher-ups: OMB's new memo grants industry's long-held wish to get a stranglehold over risk assessments that establish the case for regulatory protections.



DOWN THE RABBIT HOLE

How OMB Has Buried Risk Assessments Under Requirement After Requirement

OMB's new memorandum on risk assessment is only the latest in a series of Bush administration policies that bury risk assessments under layer after layer of requirements. The new risk memo adds so-called "Good Guidance Practices" policies (Exec. Order No. 13,422 and related bulletin) on top of the requirements already in place under the Data Quality Act Guidelines and OMB Peer Review Guidelines.





Risky Business: Sullyng Science With Politics Yet Again

RECKLESS DISREGARD

*How the New OMB Risk Memo Ignores
the Recommendations of the National Academies*

After a scathing rebuke by the National Academies' National Research Council (NRC), the Bush White House withdrew a draft one-size-fits-all policy for risk assessments. OMB's response claims to respect the NRC's recommendations but actually adds new burdens to risk assessments and sends signals that evince a reckless disregard of the expert counsel of the NRC.

What OMB is requiring in the new risk memo . . .¹

. . . was rejected by the National Academies.²

Subjecting scientific risk assessments to political OMB review . . .

- "Agencies should refer to OMB's Final Bulletin for Agency Good Guidance Practices, as well as the Peer Review Bulletin, for updated guidance regarding best practices for increasing public access and public comment concerning guidance documents and influential scientific information." (13)
- The "good guidance practices" bulletin, a supplement to Executive Order 13,422, requires review and approval by senior political appointees and OMB of "significant guidance documents," a broadly-defined universe of materials that, according to the new risk memo, now includes major risk assessments.

. . . would allow industry-biased politics to trump scientific expertise and unnecessarily delay agencies.

- "Specifically, the committee is concerned that to the extent that the implementation of the technical aspects of risk assessment will be overseen by OMB and not by the peer-review process or by agency technical managers, scientific issues may be superseded by policy considerations." (99-100)
- "More important, additional time would be added if, in addition to the peer review process, OMB were to review anew the work product even where there is an existing well-done peer review." (99)

Subjecting risk assessment to industry challenge . . .

- Declares that influential risk assessments are subject to new "good guidance practices," which require *Federal Register* notice, comment period for industry to challenge the risk assessment, and execution of a full response-to-comments document for "economically significant guidance." (13)
- Repeatedly invokes OMB guidelines pursuant to the so-called "Information Quality Act," an eleventh-hour appropriations rider requiring the establishment of processes for the public to file challenges to agency information.

. . . will politicize and delay risk assessments.

- "There is also concern that the call for peer review, with the call for public participation, in the bulletin goes beyond previously stated requirements" (99) by "calling for a response to comment package for all influential risk assessments [which] would affect the timeliness of the reports without adding improvements in the scientific quality" (99 n.32).
- "[R]equiring a federal agency to provide a rationale for why its position is preferable to positions proposed by commenters is likely to expend excessive resources and might result in less time to devote to agency risk assessments, thus affecting the quality and output of agency products." (69)
- "The committee is therefore troubled by OMB's repeated references to the Information Quality Act (IQA) and its invocation as the legal authority for OMB to issue this bulletin, that suggest that challenges to a particular risk assessment — and almost every risk assessment is open to challenge on one ground or another — will be handled through the process designed for the IQA, a process that is more a legal or policy process than a scientific one." (99)

Requiring risk assessors to consider risk management concerns . . .

- Bootstrapping the IQA Guidelines, Peer Review Guidelines, and "Good Guidance Practices" order/bulletin requires risk assessors to comply with commands based on an evaluation of how the assessment will have consequences for risk management, both by policymakers and by voluntary private sector actors (including the cost to industry of modifying its own behavior or complying with a regulation that could possibly be promulgated at some future date in response to the risk assessment).

Requiring risk assessments to focus on risk ranges rather than point estimates and to emphasize central or expected risk values . . .

- "Due to the inherent uncertainties associated with estimates of risk, presentation of a single estimate may be misleading and provide a false sense of precision. Expert panels agree that when a quantitative characterization of risk is provided, a range of plausible risk estimates should be provided." (6-7)
- Stresses that IQA Guidelines, which are bootstrapped to govern influential risk assessments, "direct the agencies to ... specify, to the extent practicable ... the expected risk or central estimate of risk for the specific populations [affected and] each appropriate upper-bound or lower-bound estimate of risk." (6)

. . . violates the fundamental principle of distinguishing between risk assessment and risk management and will unreasonably delay needed risk assessments.

- "Whether an analysis constitutes an 'influential risk assessment' may not be clear at the outset. Moreover, this standard's focus on economic impacts imposes risk management concerns on risk assessment. Arbitrarily separating risk assessments into two broad categories (influential and noninfluential) ignores the continuum of risk assessment efforts." (66)
- "A slightly different problem arises from the bulletin's requirement that risk assessments used for regulatory analysis include a variety of evaluations of alternative mitigation measures. Although risk assessors contribute information for use in risk management, this standard goes well beyond the job description of the scientist or technical person assessing the risk onto the path of risk management Not only will these requirements be resource-intensive and time-consuming, but the committee is also concerned that if they were incorporated at the primary stage of the risk assessment process (for example, identifying a hazard and determining the extent of the risk), risk assessors will be greatly delayed in doing their work." (101)

. . . threatens the quality of risk assessments.

- "The standard does not provide clear guidance on how such a range is to be defined. As a result, it may produce confusion that could erode the quality of risk assessment." (62)
- "The term *plausible risk estimate* is undefined in the bulletin. If a distribution is substantially skewed or bimodal, identifying a single estimate considered a 'plausible' estimate of the distribution is not meaningful. In that case, a 'central' estimate will not reasonably represent the distribution. When distributions reflect variability, the ambiguous term *plausible* appears to be at odds with the fundamental orientation of public-health practice and prevention, especially when the applicable laws seek to protect the most vulnerable in the population: infants, children, the elderly, and those with illnesses or predispositions to illness. Using a mean or central estimate to identify the most 'plausible' individual would undermine public-health goals." (62-63)
- "The bulletin's discussion of central and expected estimates and uncertainty is confused and prevents useful application of the standard. It is misleading to suggest as the bulletin does that 'central' and 'expected' estimates are synonymous.... [W]ithout proper definitions and context, use of the range or 'central estimate' will be misleading.... It is not in decision-makers' or society's interest to treat fundamentally different predictions as quantities that can be 'averaged.'" (67)

¹ See Office of Info. & Reg. Affs., OMB, *Updated Principles for Risk Analysis* (OMB Memo. No. M-07-24, Sept. 19, 2007), available at <<http://www.whitehouse.gov/omb/memoranda/fy2007/m07-24.pdf>>. Subsequently cited parenthetically.

² Board on Envtl. Studs. & Toxicology, Nat'l Research Council, *Scientific Review of the Proposed Risk Assessment Bulletin from the Office of Management and Budget* (National Academies P, 2007). Subsequently cited parenthetically, with citations in original removed but all other emendations noted.