Commission on Risk Assessment and Risk Management

Report on the Accomplishments of the Commission on Risk Assessment and Risk Management

by Gilbert S. Omenn, Commission Chair

Summary and Discussion

The Commission on Risk Assessment and Risk Management, which completed its mandated report to Congress on the appropriate uses of risk assessment and risk management in Federal regulatory programs in March 1997, has helped to stimulate agency policies, legislation, and private sector activities that improve risk assessment and risk management. The Commission's recommendations are cited in EPA policy changes on probabilistic analysis, risk characterization, and cumulative risk. The Food Quality Protection Act and the Safe Drinking Water Act Amendments of 1996 reflect Commission proposals. And the American Society for Testing and Materials, one of the world's largest voluntary standards developers, is developing standards for risk management by building explicitly on the Commission's Risk Management Framework.

Over the three years of its work, the Commission heard from 109 individuals at public meetings around the country, received 130 formal comments on our Draft Report, and consulted with agency staff, Administration officials, and Members of Congress and their staff. Drawing upon the information, knowledge, and expertise provided by these people, the Commission proposed its Framework for Environmental Health Risk Management and made specific recommendations for the many federal regulatory environmental, health, and safety programs that deal with risk management. My colleagues and I are pleased to offer this commentary about the origins, insights, and impact of the Commission's

work.

Congress mandated this Commission, which held its first meeting in May 1994, as part of the far-reaching Clean Air Act Amendments of 1990, together with a National Research Council (NRC) study that became the *Science and Judgment in Risk Assessment* report of 1994. In mandating the Commission and NRC report, Congress was motivated by a general interest in more consistent and "more scientific" use of risk-based methods, and by the specific dilemma of how to deal with residual emissions and residual risks from Section 112 hazardous air pollutants after the implementation during the 1990's of the new Clean Air Act scheme for technology-based controls on stationary sources of air pollutants.

Launching the Commission involved a complex political process. The six Congressional appointments (Norman Anderson, John Doull, Joshua Lederberg, Gil Omenn, David Rall, Virginia Weldon) and the National Academy of Sciences appointment (Bernard Goldstein) were not all announced until 1993. President Bush's three appointments lapsed with the change of administration. Several months later, President Clinton appointed successors (Peter Chiu, Alan Kessler, Sheila McGuire) and, in fact, McGuire's appointment became effective only after the Commission's first meeting, at which Barbara Bankoff participated as a Bush appointee. EPA provided the necessary administrative assistance for us to operate. Our huge substantive and logistical workload was accomplished with three dedicated staff. Gail Charnley, a toxicologist and risk assessor with extensive experience at the National Research Council; Sharon Newsome, a vice president at the National Wildlife Federation; and Joanna Foellmer, administrative assistant and Designated Federal Official. The deferred start worked well because the NRC Committee was completing its work on risk assessment at the time the Commission was defining its charge.

The Congressional mandate was focussed explicitly on human health hazards from chronic exposures to environmental agents. We were directed to examine (1) the uses and limitations of risk assessment in environmental decision-making; (2) the appropriate exposure scenarios for estimation of risks; (3) the most effective ways to describe or explain uncertainties; (4) various policy issues in risk management; and (5) inconsistencies across agencies. The roles of peer review, judicial review, and economic analysis became contentious during the 1995 Congressional debates over regulatory reform legislation, leading to requests from both ends of Pennsylvania Avenue for attention to these matters. Injuries due to unsafe conditions, acute illnesses from toxic agents, risks from radiation and infection, and hazards to ecosystems were not included in our charge.

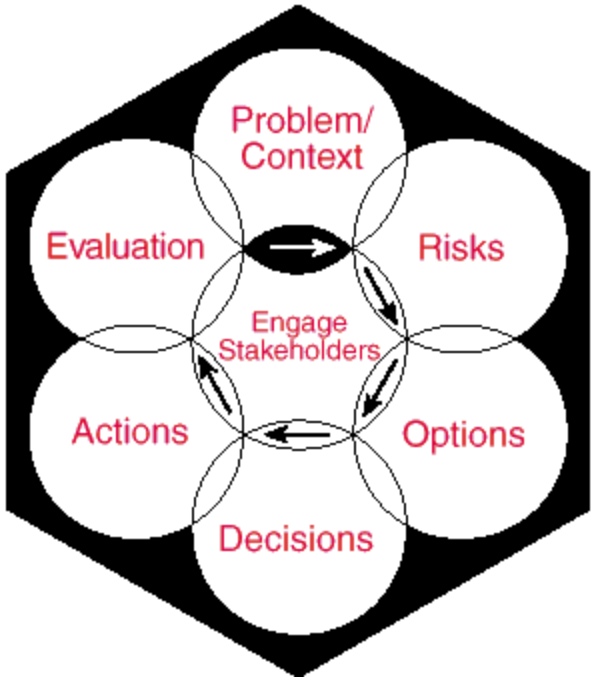
Based on deliberations with stakeholders, we decided that, had the Congress been issuing its charge in 1994 instead of 1990, surely the lawmakers would have been interested in the relevance of the risk assessment/risk management (RA/RM) approach to ecological hazards. So we investigated ecological risk assessment. Also, we felt that radiation and microorganisms pose hazards that should be considered together with chemical hazards, especially when there are coexistent contamination problems (as at Department of Energy and numerous industrial sites, and in medical waste streams) and when chemical risks must be balanced against infectious disease risk (as in chlorination of drinking water to control bacterial and viral contamination). Most importantly, we decided that our greatest opportunity to make an impact was in the area of risk management.

Numerous reports and agency initiatives already addressed risk assessment. But the overriding process of risk management had not been examined systematically. We aimed to create a framework for risk management that might take hold as had the framework for risk assessment embodied in "The Red Book" of 1983, the NRC report *Risk Assessment in the Federal Government: Managing the Process.* As in that precedent, we do not claim originality for all of the ideas in the Framework; we found great resonance, however, around the country and among the constituencies interested in our work, for the crucial concepts espoused in our Draft Report.

The first clear, external indication of the interest that would be generated by our Risk Management Framework came with the news stories in *The New York Times and The Washington Post* on June 14, 1996, reporting on the release of our Draft Report, *Risk Assessment and Risk Management in Regulatory Decision-making.* The headline in *The New York Times* read "New System of Assessing Health Risks Is Urged." The six-step process begins with explicitly formulating a problem and putting it in public health and ecological context before launching into risk assessment and economic analysis to define options for action, and ends with an evaluation of the effectiveness of the action. Engaging stakeholders from the start of the six steps is essential. Not only do community stakeholders have a right-to-know; they often, we learned at bimonthly hearings around the country, have crucial knowledge about sources of exposure, cultural practices, and behavioral patterns that are omitted in standard risk-assessment models. Those omissions frequently lead to outrage when risk assessments and risk-based decisions are presented belatedly to such stakeholders. The hexagon below shows our six-step process, with the central role of stakeholders.

First, we committed ourselves to overcoming the predominant regulatory strategy of dealing with one chemical at a time, in one environmental medium (air, water, food, soil) at a time, and each risk (cancer, birth defects, eco-hazards) in isolation. Repeatedly, non-experts challenged us as commissioners to address multiple exposures and multiple effects. Therefore, we gave particular attention to the testing and evaluation of significant environmental mixtures. We do not recommend testing every conceivable combination of every chemical; that would be ridiculous. But it is feasible to test particular air, water, soil, or food samples for overall effects using *in vitro* or animal test systems. We know that such mixtures vary over time and place, but representative samples can be and have been tested. Examples are diesel exhausts and Los Angeles smog. We are pleased that EPA recognizes this need and is initiating complex mixtures testing program.

It is important to develop a better experimental basis for general assumptions about additivity of risks of various kinds and about potential synergisms (e.g., smoking combined with asbestos exposures multiplies the risk of lung cancer). Here we must overcome a natural predilection among scientists to study purified single chemicals and to focus in great detail on one or another of what may be multiple effects of agents. We challenge the agencies and the Congress to cross statutory lines, address overlaps, and use the combination of agency discretion and Congressional oversight to put an emphasis on multi-media, multi-source, multi-agent, and multi-risk context for analysis and decisions. The EPA Cumulative Exposure Project begun recently is a step in the right direction (See "Accomplishments").



Examining multiple risks creates a need for a practicable way to compare risks. As a nation, we are bedeviled by a scientific dichotomy in the assumptions about the dose-response relationship for chemicals that cause cancers and chemicals (sometimes the same chemicals) that cause brain damage, reproductive impairments, lung damage, or other serious noncancer effects. Risk of cancer is generally considered to reach zero only at zero dose (zero exposure), while other risks are thought to disappear at some appreciable "threshold" level. The 1996 EPA proposed Cancer Risk Assessment guidelines take a big step forward in identifying criteria for cancer-causing agents that deviate from the linear extrapolation to zero dose and proposing greater use of a margin-of-exposure approach in discussing relative risks.

Second, our focus on risk management reminds us all that there are other crucial elements in decision-making besides the scientific evidence and evaluation of known or potential risks--namely, statutory requirements, technical feasibility, distribution of benefits and costs in the population and among interest groups, political philosophies and commitments, and social and cultural perspectives on the nature and extent of a risk and comparisons with other risks. EPA recognizes the importance of these factors in risk management and, with acknowledgment of the Commission's recommendation, has changed its Risk Characterization Policy to require information about social, economic, cultural values, and other factors, along with scientific data, in risk characterizations. Similarly, the American Public Health Association referenced the Commission's proposals in their June, 1997 comments on the National Food Safety Initiative. The need for more than scientific information led the EPA Science Advisory Board to cite Commission recommendations on stakeholder participation and inclusion of social and other values when explaining why science alone doesn't provide a basis for combining ecological and human health risk rankings.

Nevertheless, scientific investigation and evaluation of risk are essential to determine whether there is any problem at all. If the chemical under consideration does not produce in animals or humans any significant adverse effects, leads to no current or foreseeable exposures, or produces no adverse effects at levels of exposures people actually encounter, much of the subsequent analysis and decision-making process becomes irrelevant and should be truncated. In any case, the intensity of risk assessment, uncertainty analysis, economic analysis, and peer review should be scaled to the scientific and social

significance of the issues.

In Volume 2, *Risk Assessment and Risk Management in Regulatory Decision-Making* (1997), we list several tumor responses in rodents that appear to fall into the EPA cancer risk assessment category of responses unlikely to be predictive of cancer risk for humans--so long as a chemical is adequately investigated, only this specific tumor is produced in test animals, and recognized mechanisms are demonstrated to be responsible. Also, we endorse the use of probabilistic distributions of exposure estimates, which can be verified and related to particular subgroups in the population, but we are cautious about routine use of quantitative uncertainty methods for dose-response curves and resulting risk estimates, where good narratives may be much more useful, at least right now. EPA's new Probabilistic Risk Analysis Policy cites the Commission's recommendation and other EPA policy documents in support of the new policy.

Third, we recognize in the risk management world the overriding need to sustain the gains achieved in the last 25 years in environmental and health protection, while implementing much more efficient and cost-effective ways of dealing with ongoing and new problems. Setting protective goals in terms of risk reduction and establishing "bright lines" for emission, contamination, and exposure levels that can be measured should be the responsibility of regulatory and health agencies. The best ways to meet those goals and compliance standards or permitted levels should be left to responsible parties in a broad stakeholder process, whenever feasible and credible. We applaud experiments to employ such a process, while noting some serious deficiencies in present implementation.

We also recognize that the devolution of responsibility to regional, state, and local levels demands that much more work be done to better define the respective roles of the public, private, and not-for-profit sectors in solving the diverse problems addressed.

Fourth, we decided about a year into our work that our recommendations would be much more salient if we moved beyond general frameworks and recommendations about toxicity assessment, exposure assessment, variation in susceptibility, description of variability and uncertainty, comparisons of risks, use of economic analyses, peer review, judicial review, and alternatives to command-and-control regulation. We decided to offer findings and recommendations program-by-program for the EPA, Food & Drug Administration, Occupational Safety and Health Administration, National Institute for Occupational Safety & Health, and the Departments of Agriculture, Energy, and Defense. Such specific recommendations. made the Commission Report salient to many more individuals and organizations. Recommendations for a win-win modification of the Delaney clause with regard to pesticide residues and for the Safe Drinking Water Act were adopted by the Congress in productive amendments to those laws late in 1996. The Resource Conservation & Recovery Act land-ban provision that so complicated Superfund cleanups was modified. The Administration took long-awaited action to bring modern methods to the prevention of microbial contamination of meats and other foods. And the Commission was consulted by House and Senate Committees during consideration of regulatory reform legislation and Superfund reauthorization legislation throughout the 104th and 105th Congresses.

The most important of our program-specific recommendations deal with Section 112 of the Clean Air Act, the origin of our Commission's mandate. We presented a tiered approach to the assessment of residual emissions and risk after Maximum Achievable Control Technology requirements are implemented during this decade. In presenting this approach, we illustrated the context, stakeholder, margin-of-exposure, and comparative risk principles that are key to our overall recommendations, calling for emissions and risk from a single source or sentinel chemical to be put into the context of all sources of those chemicals in its geographic area. Using this context approach, the risk attributable to that source can be estimated and the benefit of further reducing its emissions can be better appreciated relative to all significant sources. Then we compare the residual risks from Section 112 hazardous air

pollutants and Section 109 criteria air pollutants (particles, sulfur oxides, nitrogen oxides, carbon monoxide, ozone, and lead). In most areas, the margin of exposure (the ratio between levels that clearly affect some appreciable percentage of people or laboratory animals and the current levels) is very small to none for the criteria air pollutants. In contrast, the margin of exposure between exposures that would cause cancer in 10% of a population and the exposures associated with estimated cancer risks of 1-in-10,000 to 1-in-a-million after the technology controls are in place would be 1,000 to 100,000. Such considerations put a premium on EPA's 1997 proposals for better controlling fine particles and ambient ozone levels.

On another air pollution issue, the Commission highlighted the discrepancy between extensively regulated outdoor air pollution and indoor air pollution. Indoor air can pose a substantial risk to human health but receives little attention and remains largely unregulated. EPA has heeded the call of the Commission and other organizations by forming an Indoor Air Committee.

As a general matter, we stress the practical value of expressing risks in terms of risk reduction, rather than fighting about abstruse estimates of absolute risk levels and the attendant methods for estimating the uncertainties in the estimates of risk levels. In general we may make more progress earlier and with greater cost-effectiveness by moving stepwise in the right direction, instead of paralyzing action in analyses and litigation about ultimate acceptable risk levels.

Finally, in the responses to our Framework as it was described in the 1996 Draft Report, we realized that people were generally supportive, but genuinely skeptical about the feasibility and desirability of engaging stakeholders and putting problems into context. They wanted the concept fleshed out. Thus, in producing our Final Report, we created Volume 1, *Framework for Environmental Health Risk Management*. Volume 1 is a 50-page document strictly focussed on the Framework, to explain the six-step process, provide guidance for involvement of stakeholders, and give real-world examples of situations where problems were put into context in partnership with stakeholders or where this was not done. We are encouraged that so many people have found this reader-friendly "thin report" so persuasive. For example, we were gratified by the *Los Angeles Times* coverage on January 29, 1997 of the release of Volume 1, highlighting this new way for assessing and managing pollution hazards. Volume 1 was also reported widely by the wire services of Associated Press, Reuter, and United Press International and such regional papers as *St. Louis-Post Dispatch, Kansas City Star, Portland Press Herald,* and *The Record* of Bergen, New Jersey.

Volume 2 is the complete revision of our Draft Report, including a summary of comments and responses to comments. This detailed document received very supportive coverage in the trade press. *Risk Policy Report,* Bureau of National Affairs newsletters, *Environmental Health Letter, Inside EPA's* newsletters, *The Nation's Health, Chemical and Engineering News,* and many other periodicals reported on the Commission's activities and recommendations regularly (see "Media Coverage").

We issued our two-volume Final Report five months ahead of our scheduled ending time, generating the possibly unprecedented opportunity to work with others to pursue implementation of our recommendations, rather than submitting our final report and evaporating as so many Commissions have! As in the formulation of our recommendations, Commissioners and staff made a concerted effort to speak to organizations and individuals most likely to have an interest and an opportunity to make use of our findings and recommendations (see "Outreach"). For example, Gail Charnley spoke to over 100 state and local agency staff at a meeting sponsored by the National Governors Association. Gil Omenn presented the Commission's recommendations to the Society for Risk Analysis' 1996 annual meeting of more than 600 attendees. John Doull keynoted a risk assessment symposium sponsored by the U.S. Army Chemical and Biological Defense Command. Even though the Commission will have disbanded at the end of August, Peter Chiu will speak to the November annual meeting of the Society of

Environmental Toxicology and Chemistry, and the outcomes of the August 8, 1997, public meeting on putting environmental problems in public health context, attended by 200 people, will be featured at the December 1997 Society for Risk Analysis Annual Meeting.

All of our documents, including consultant papers, can be downloaded from the Internet at www.riskworld.com. The Government Printing Office at 202-512-1800 will provide Volume 1 for $6.00 (stock number 055-000-00567-2) and Volume 2 for $19.00 (stock number 055-00000568-1). Volume 1 is being translated into Japanese and will be available from Secretariate of Mediation Committee for Environmental Affairs, Sourifu Kougaitou Chousei-iinkai, 1-6-1 Nagata-chou, Chiyoda-ku Tyoko, Japan.

The Commissioners and staff thank the many people who gave generously of their time and expertise to enrich our deliberations. We retire satisfied that we have made a difference and have contributed to the improvement of risk assessment and risk management practices in this country and internationally.

Accomplishments

The following policies, papers, and projects are either consistent with Commission recommendations or specifically cited the Commission's work.

The Commission's recommendations had an impact on the Safe Drinking Water Act Amendments of 1996, which reflect the Commission's emphasis on including many factors risks, costs, benefits, feasibility, and social and cultural concerns -- in risk management decisionmaking.

EPA Science Advisory Board's Integrated Risk Project Report (in press, expected to be released December 1997) cites Commission recommendations on stakeholder participation and inclusion of social and other values in explanation of why science alone doesn't provide a basis for combining ecological and health risk rankings.

EPA Cumulative Risk Guidance Federal Register incorporates Commission recommendations on multiple risks and use of stakeholders in scoping and problem formulation stages to help with identifying cumulative and multiple risks.

EPA broadened Risk Characterization Policy citing Commission recommendation to include social, economic, public values, and other factors along with scientific data.

EPA opens Office of Children's Health Protection consistent with Commission recommendation to consider sensitive and highly exposed populations.

EPA's Guidance on Probabilistic Analysis cites Commission report in justification for developing guidance on use of Monte Carlo analysis in risk assessment.

EPA forms Indoor Air Committee with acknowledgment of Commission's recommendation.

An Assessment of EPA's Reinvention, report by House of Representatives, Committee on Transportation

and Infrastructure, September 17,1996 quoted the Commission's contractor report on risk estimates of DCE.

Comments on EPA's Draft Strategic Plan by Chairmen Bliley of Commerce Committee, Sensenbrenner, Jr. of Science Committee, Burton of Government Reform and Oversight Committee, and Shuster of Transportation and Infrastructure Committee, July 28, 1997.

American Public Association Health comments on National Food Safety Initiative cite Commission's emphasis on scientifically sound, cost-effective, integrated actions that reduce or prevent risks while taking into account social, cultural, ethical, political, and legal considerations.

American Public Health Association and National Association of County and City Health Officials testimony on Superfund reauthorization before the House Transportation and Infrastructure Committee by Bailus Walker cites Commission recommendation to include all stakeholders as early as possible in risk management decisions.

American Society for Testing and Materials adopted a modified version of the Commission's six-step Framework and is developing a list of nine principles for risk management that builds on the Commission's principles outlined in Volume 1of Final Report.

"Achieving, not setting, air quality standards is the real issue," *The San Diego Union Tribune*, June 15, 1997, Op-ed by Debra S. Knopman, cites the Commission's emphasis on indoor air pollution as significant but unaddressed by current regulatory programs.

"Promises to Keep," *The New Democrat,* May/June 1997, editorial by Debra S. Knopman, cites the work of the Commission.

"Risk Prioritization: Moving the Debate Forward" by Thomas D. Hopkins, cites Commission's Draft Report extensively, and Rhomberg, Kopp, and Crouch reports for the Commission in a paper prepared for The Climate Change Policy, Risk Prioritization, and U.S. Economic Growth, Symposium sponsored by American Council for Capital Formation Center for Policy Research, Sept. 11, 1996

"Regulatory 'Reform or Improvement,'" by Robert Barnard and Donald L. Morgan in May 23, 1997 issue of *Risk Policy Report* lauds work of the Commission and urges Congress to use it as a blueprint for regulatory reform legislation.

The Risk Commission's Framework for Risk Management and stakeholder recommendations and process cited in the draft final report from Enterprise for The Environment, August 1997.

Outreach

Commission members and staff presented information on our endeavors to the following organizations.

"Risk Assessment: improving the Science and the Art," Arkansas Toxicology Symposium, November 1994 - Gail Charnley.

"Regulatory Reform Legislation," Society of Toxicology Annual Meeting, March 1995 - Gail Charnley.

"Impact of 104th Congress on Health Risk Assessment," Society for Risk Analysis Washington Chapter Meeting, March 1995 - Gail Charnley.

"Women in Government," American Industrial Health Council April 1995 - Gail Charnley.

"Risk Assessment Issues for Sensitive Human Populations," Tri-services Toxicology Group Conference, April 1995 - Gail Charnley.

"Risk Assessment/Risk Management Commission, Regulatory Reform," Wright State University Institute for Environmental Quality, April 1995 - Gail Charnley.

"The Turning Point: An Environmental Revolution on the Horizon," League of Conservation Voters, April 1995 - Sharon Newsome.

"Pollution Prevention Conference Partnerships," New York State Department of Environmental Conservation, May 1995 - Gail Charnley.

"The President's 25 Point 'Reinventing Environmental Regulation'," National Environmental Policy Institute, May 1995 - Sharon Newsome.

"Commission Work and Regulatory Reform Issues," Local Society for Risk Analysis Meeting, June 1995 - Gail Charnley.

"Cultural Components of Risk Assessment and Risk Management," Symposium on Integration of Yakama Cultural Values with Salmon Restoration, Yakama Indian Nation, July 1995 - Peter Chiu.

"Holistic Approaches to Risk Assessment and Risk Management," The Emerging Work of the Presidential/Congressional Commission on Risk Assessment and Risk Management Symposium, Yakama Nations - Gilbert Omenn.

"The Role of Science in Risk Assessment and Risk Management," Institute Society for Toxicology meeting, July 1995 - Gilbert Omenn.

"Improving Risk Assessment and Risk Management in Federal Regulatory Programs," ILSI Health and Environmental Sciences Institute, October 1995 - Gail Charnley.

"Risk Assessment 1995: Where Does the Great Risk Debate Stand Now?," Inside EPA and Risk Policy Report, October 1995 - Gail Charnley.

"Risk Based Regulation: Possibilities and Pitfalls," American Nuclear Society Winter Meeting, October 1995 - Peter Chiu.

"The Impact of Regulatory Reform on the Science of Risk Assessment," HazMat/West Environmental Management and Technology Conference, November 1995 - Gail Charnley.

"Impact of Regulatory Reform Legislation and Generating Uncertain Risk Estimates," Society for Risk Analysis Annual Meeting, December 1995 - Gail Charnley.

"Framework for Environmental Risk - Management Decision-Making," Society for Risk Analysis Annual Meeting, December 1995 - Peter Chiu, Gail Charnley, Gilbert Omenn.

"Improving Risk Assessment and Risk Management in Federal Regulatory Programs," Society of Toxicology Annual Meeting, March 1996 - Gail Charnley.

"Findings and Recommendations from the Presidential/Congressional Commission on Risk Assessment and Risk Management," Environmental Mutagen Society, 27th Annual Scientific Meeting, March 1996 - Gilbert Omenn.

"The Chemical Industry, Health Sciences, and Risk Regulation," Chemical Industry Institute of Toxicology, April 1996 - John Doull

"Reducing Health Risks in the United States: Transforming the World of Environmental Regulation," CIIT, The Chemical Industry, Health Science, and Risk Regulation, April 1996 - Gil Omenn.

"Harmonization of State/Federal Approaches to Environmental Risk," Michigan State University, May 1996 - Gail Charnley.

European Society for Risk Analysis Annual Meeting, June 1996 - Gail Charnley.

"Commission's Draft Recommendations," Department of Agriculture Office of Risk Assessment and Cost-Benefit Analysis and the Washington, DC area Society for Risk Analysis Chapter, June 1996 - Gail Charnley.

"Inside Washington: Business and Public Policy," Brookings Institution, June 1996 - Gail Charnley.

"Risk Assessment and Risk Management's Draft Report," National Academy of Sciences Board on Environmental Studies and Toxicology meeting, July 1996 - Gail Charnley.

"Findings and Recommendations from the Presidential/Congressional Commission on Risk Assessment/Risk Management," ILSI Risk Sciences Institute Forum, July 1996 - Gilbert Omenn.

"Keynote: The Role of Environmental Health in Sustainable Economics and Healthy Communities," Oslo Conference of the major cities, Norway, August 1996 - Gilbert Omenn.

"Risk Policy" Significant Findings of the President's Commission on Risk Assessment and Risk Management," International Society for Risk Analysis, Health Risk Assessment: Current Issues, Washington, DC, September 1996 - Gilbert Omenn.

AAAS-EPA Fellows, September 1996 - Gail Charnley.

"Conference on Risk Assessment," Texas International Business Communications, "Conference on Risk Assessment," October 1996 - Gail Charnley.

"Risk Management Framework," Resources for the Future, October 1996 - Gilbert Omenn.

"The Risk Commission," University of California Workshop on Risk, October 1996 - Peter Chiu.

"Report of the Commission on Risk Assessment and Risk Management," Environmental Corporate Counsel Summit, Washington, DC, October 1996 - Gilbert Omenn.

New England Chapter of the Society for Risk Analysis, October 1996 - Norman Anderson.

The American College of Toxicology Distinguished Service Award Lecture - John Doull.

"Risk in the Republic: Comparative Risk Analysis and Public Policy, Cummings Colloquim," Duke Law School, Nicholas School of the Environment, and Society for Risk Analysis, November 1996 - Gail Charnley.

"Building an Integrated, Holistic Framework for Risk Management Decisions," presented at the American Public Health Association Annual Meeting, November 1996 - Peter Chiu, Gail Charnley, Bernard Goldstein, Gilbert Omenn.

"Commission's Risk Management Framework," George Mason University Law School, November 1996 - Gail Charnley.

"Putting Environmental Risks in a Public Health Context," *Public Health Reports,* November/December 1996 - Gilbert Omenn

American Water Works Association, Annual Meeting, November 1996 - Gail Charnley.

"Risk Communication Symposium," Agency for Toxic Substances and Disease Registry, December 1996 - Bernard Goldstein.

"Risk Policy Briefing," sponsored by Risk Education Project of American Chemical Society, December 1996 - Sharon Newsome.

"Carcinogenesis and Risk Assessment: Recommendations from the Risk Commission," 10th International Barton Creek Conference on Carcinogenesis and Risk Assessment, December 1996 - Gil Omenn.

"Risk Assessment and Risk Management in Regulatory Decision-Making," Society for Risk Analysis, New Orleans, December 1996 - Gil Omenn, Gail Charnley.

"Regulatory Issues in Crop Production: Scientific Uncertainty and Regulation," Tufts University, February 1997 - Gail Charnley.

"Toxicology Forum: Ethanol Toxicity Session," February 1997 - Gail Charnley.

"Keynote: Risks, Research, Health Promotion and Disease Prevention," Grantmakers in Health, Annual Meeting, February, 1997 - Gilbert Omenn.

"Comprehensive Risk Management Can Work at the Local/Regional Level," American Association for the Advancement of Science Annual Meeting, February 1997 - Peter Chiu

"Science-based risk management in regulatory agencies; assessing Risk Commission recommendations,"

February 1997 - Gilbert Omenn, Peter Chiu.

Risk Assessment and Policy Association, Annual Meeting, March 1997 - Gail Charnley.

"Risk Assessment Mini-Course," Drexel University, March 1997 - Gail Charnley.

Risk Commission recommendations of special interest to toxicologists and risk assessors. Society of Toxicology Annual Meeting, March 1997 - Gilbert Omenn.

"EPA's Science Advisory Board," Executive Committee Meeting, April 1997 - Bernard Goldstein.

"The Role of Risk Assessment in Developing Reasonable Policy and Regulation," session for WM Symposia, Inc., April 1997 - Gail Charnley.

"Law, Science and Technology Seminar," George Washington University School of Law, April 1997 - Gail Charnley.

"Toxicology in Risk Assessment Symposium," U.S. Army Chemical and Biological Defense Command, May 1997 - John Doull, Gail Charnley.

Association of Metropolitan Sewerage Agencies, Annual Meeting, May 1997 - Sharon Newsome.

Health Effects Institute Annual Meeting, May 1997 - Gilbert Omenn.

"Superfund Risk Assessors Annual Meeting," EPA Regional Offices, June 1997 - John Doull.

"Risk Information System on Chemicals," National Environmental Policy Institute, June 1997 - Sharon Newsome.

"Conference on State and Local Risk-Based Decision-Making," National Governors' Association June 1997 - Gail Charnley.

"The Future of Risk Assessment and Risk Management," European Society for Risk Analysis, Annual Meeting, June 1997 - Gail Charnley.

"Federation on State and Tribal Toxics Action," National Conference of State Legislators' meeting, June 1997 - Gail Charnley.

"Tribal Risk Assessment Meeting," National Congress of American Indians Nuclear Waste Programs, June 1997 - Gail Charnley.

"Risk Commission recommendations: Implications for the Department of Energy," Constitium for risk evaluation annual meeting with stakeholder participation, June 1997 - Bernard Goldstein, Gilbert Omenn.

"Changing Needs in Occupational Medicine," Department of Energy, July 27 1997- Bernard Goldstein.

National Association of County and City Health Officials, Annual Meeting, July 1997 - Norman Anderson.

"Creating a Strategy for Science-Based National Policy," Council of Scientific Society Presidents, July 1997 - Bernard Goldstein.

"New Approaches to Carcinogen Assessment in the Context of Risk Assessment," Aspen Cancer Biology Conference, July 1997 - Gilbert Omenn.

"Integrating Risks, Restoration, and Future Uses," Savannah River Citizens Advisory Committee, September 1997 - Bernard Goldstein.

"Risk Commission Recommendations for EPA," Region X Meeting, September 1997- Gilbert Omenn.

"Applications of the Risk Commission's Framework for Environmental Health Risk Management," on behalf of the Consortium for Risk Assessment with Stakeholder Participation (CRESP), September 4, 1997 - Seattle, WA.- Gilbert Omenn and Bernard Goldstein.

"Applications of the Risk Commission's Framework for Environmental Health Risk Management," presentation to the U. S. Environmental Protection Agency Region 10, September 2, 1997 - Seattle, WA.- Gilbert Omenn.

"1997 Distinguished Toxicology Lecture," sponsored by University of Oklahoma Health Sciences Center, October 1997 - John Doull.

"Building the Global Environment Technology Communication," Society of Environmental Toxicology and Chemistry, November 1997 - Peter Chiu and Gilbert Omenn.

Sample RAMC Scientific Publications

Published Abstracts

Omenn GS, Chiu PY, Goldman L.R., Stratton JW, Roe D, Sigman DD. Science-based risk management in regulatory agencies: assessing Risk Commission recommendations. AAAS Annual Meeting, Feb. 14-15, 1997; p.A-60.

Omenn GS. Risk assessment, risk management, and holistic thinking. AAAS Annual Meeting, Feb. 14-16,1997; p.A-59.

Omenn GS. Risk Commission recommendations of special interest to toxicologists and risk assessors. Society of Toxicology Annual Meeting, March 1997. The Toxicologist 1997;36:51-5.

Omenn GS. New approaches to carcinogen assessment in the context of risk assessment. 12th Aspen Cancer Biology Conference: Mechanisms of Toxicity and Carcinogenesis, July 1997; Toxicologic pathology (in press).

Charnley G, Omenn GS. Improving risk assessment and risk management in federal regulatory programs. Society of Toxicology, March 1996, Anaheim, CA.

Omenn GS. Making science count in risk management decisions. Environmental Mutagen Society Annual Meeting, March 1996, Victoria, B.C., Canada.

Omenn GS. The mandate and status of the President's Commission on Risk Assessment and Risk Management. ILSI, January 1995, Cancun, Mexico; p.37-38.

Omenn GS, Chiu P. Framework for environmental risk-management decision-making. 18th SETAC Annual Meeting: Bridging the Global Environment: Technology, Communication, and Education. November 1997, San Francisco (in press).

Publications

Omenn GS. Can systematic, integrated risk assessment with full stakeholder participation enhance cleanup at DOE's sites? In: Gee GW, Wing R, editors: The 1994 Herbert H. Parker Lecture presented at the Thirty-Third Hanford Symposium on Health and the Environment. Insitu remediation: scientific basis for current and future technologies. Battelle Press; 1994, Part 1.

Omenn GS. Progress in science-based risk assessment and risk management. Technology: Journal of the Franklin Institute 1994; 331A:21-17.

Omenn GS. Variation in susceptibility as a key parameter in risk assessment and risk communication: policy aspects. In: Walker C, Groopman J, Slaga TJ, Klein-Szanto A, editors.

Susceptibility: Impact on Risk Assessment Progress in Clinical and Biological Research 1996:395:235-247.

Omenn GS. Public Health Reports, "Putting Environmental Risks in a Public Health Context," November/December, 1996, Vol. III, p.514-516.

Ovhanian EV, Moore JA, Fowle III JR, Omenn GS, Lewis, SC, Gray GM, North DW. Workshop overview. Risk characterization: a bridge to informed decision making. Fundamentals and Applied Toxicology (in press).

Omenn GS. Insights from the Risk Commission. Risk Policy Report (in press).

Media Coverage

(The *Risk Policy Report* can be called the newsletter of record for the Commission on Risk Assessment and Risk Management. Numerous articles covering Commission activities can be found in issues from January, 1995 through September, 1997.]

Environment Week, "Upcoming Risk-Commission Report Backs Margin-of-Exposure Method," May 20, 1996, p. 319.

RiskWorld Internet Home Page, "Federal Commission Report Redefines Risk Management," June 13, 1996.

The New York Times, "New System of Assessing Health Risks Is Urged, " Gina Kolata, June 14, 1996

The Washington Post, "Panel Criticizes Government's Regulation of Health Risks," Curt Suplee, June 14, 1996.

The Bureau of National Affairs, "Panel Recommends Standard Process For Federal Risk Management Decisions," Sara Thurin Rollin, June 14, 1996, A-6. no. 115.

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