

TITLE Adaptive Risk Governance in Biotechnology:
Looking Back at Transfats, Looking Ahead on Pharmaceuticals and Synthetic Biology

SPEAKER Kenneth A. Oye
Associate Professor of Engineering Systems and Political Science
Massachusetts Institute of Technology

ABSTRACT: This presentation offers qualified support for adaptive approaches to risk governance under conditions of uncertainty, complexity and controversy. From a Bayesian perspective, the combination of early engagement with risks and systematic reassessment of policies based on emerging information offers an ideal approach to risk governance. However, adaptive strategies face significant political, economic and epistemic challenges. To illustrate the potential and limits of adaptive approaches to risk governance, this presentation features a cautionary tale on transfats and evolving current cases on pharmaceuticals and synthetic biology.

Transfats: Manufacturers and regulators in the US and Europe substituted transfats for saturated fats to extend product shelf life and reduce coronary heart disease. This case examines the fifty year lag between early reports on adverse health effects and revisions in dietary standards, with emphasis on sources of dysfunction in research funding and in the integration of research results into policy.

Pharmaceuticals: Extraordinary advances in the life sciences have not been matched by corresponding advances in delivered pharmaceuticals. This forward looking case compares established binary approaches to assessing and addressing drug safety, efficacy, and effectiveness with current proposals for more adaptive approaches to drug licensing from the EMA, FDA and Health Canada.

Synthetic Biology: The rapid development of this field has been driven by exponential advances in DNA sequencing and synthesis and by the appeal of applications in materials production, agriculture, medicine, remediation, and restoration. This forward looking case examines adaptive approaches to assessing and addressing environmental, health and security risks of synthetic biology, with reports on work by the UN BWC and WHO; by NSF, EPA, HHS, DARPA, FBI, DHS and State; by transnational consortia IGSC and IASB; and by the Sloan Foundation, MIT and the Woodrow Wilson Center and iGEM.

BIOSKETCH: Kenneth Oye is Director of the MIT Program on Emerging Technologies (PoET) and Associate Professor of Political Science and Engineering Systems, with work in international relations and technology policy. He is a PI in the NSF Synthetic Biology Engineering Research Center (SynBERC); PI on “Creating a Research Agenda on Ecological Implications of Synthetic Biology” funded by NSF Division of Cellular and Molecular Biology, the Division of Environmental Biology, and Engineering Directorate; and regulatory research lead at the MIT Center for Biomedical Innovation. He currently serves as a member of the NRC Board on Global Science and Technology, chair of the iGEM Safety Committee, and a member of the International Risk Governance Council Scientific Advisory Board. In 2012-2013, he has served as an invited expert on pharmaceuticals innovation with the President’s Council of Advisors on Science and Technology (PCAST) and as a panelist for the World Health Organization consultation on Dual Use Research of Concern. His books include *Cooperation under Anarchy*, *Economic Discrimination and Political Exchange*, and four volumes on American foreign policy. His articles include pieces on US adaptive EHS regulation in *Technology Forecasting and Social Change*, on drug licensing in *Clinical Pharmacology and Therapeutics*, on biosecurity in *Politics and the Life Sciences*, and on techno-libertarianism in *Issues in Science and Technology*, with forthcoming pieces on biosecurity in *ACS Synthetic Biology* and on environmental effects of synthetic biology in *Journal of Environmental Sciences*.