Expert Workshop on Innovation and Adaptive Governance in Biotechnology

Thursday 10 January 2013 – 08:30 - 12:15
School of Public Policy and Management, Tsinghua University – Third floor

Workshop Description

Technology development strategies and risk governance policies are commonly treated as separate spheres. **This workshop will focus on how the location, pace and diffusion of technological innovation are affected by the management of associated risks.**

In some cases, precautionary approaches to risk governance displace or forestall technological innovation. Past examples include European regulations on genetically modified crops and US limitations on stem cell research. In other cases, risks are under-addressed until health, environment, and/or security are compromised, with public alarm limiting acceptance. Past examples include Japan's shut down of nuclear power post-Fukushima and the US's stasis on gene therapy after early patient deaths. Neither approach is satisfactory.

Discussion at this workshop will focus on a third way, **adaptive risk governance for the advancement of technological innovation**, which is *pro-active*, with the emphasis on engaging with risks before rather than after crises are manifest, and *adaptive*, with the emphasis on adjusting policy to take account of emerging information on benefits and risks, as well as on the advancement of the knowledge base.

The workshop will provide an introduction on the relationship between innovation and risk management and then focus on applications to pharmaceuticals and synthetic biology:

• *The number of new molecular entities emerging from developmental and licensing pipelines has been declining and the cost of drug development has been rising. Extraordinary advances in the life sciences have not been matched by corresponding advances in pharmaceuticals, and the number of available therapeutics has fallen short of the promise of biologicals. This session will examine how the governance of risks, efficacy, and effectiveness of drugs affect pharmaceuticals innovation.*

• *Synthetic biology rests on revolutionary advances in DNA sequencing and synthesis technologies. It seeks to do biological engineering with standardised biological parts, modularised design, and routine methods of assembly. By emphasising standardisation and modularity, synthetic biologists seek to cut costs by permitting outsourcing, to reduce barriers to entry by reducing the requisite skill levels, and to extend the range of useful applications of biological engineering. This session will examine how the regulation of risks associated with DNA synthesis and synthetic biology affect the development and diffusion of advanced biotechnologies.*

In addition to discussing about adaptive governance, the workshop will review how national approaches and cross-national differences in risk governance, in relation to new forms of innovation in biotechnology, affect patterns of national economic development and international exposure to common risks.

Suggested background reading: Adaptive Licensing: Taking the Next Step in the Evolution of Drug Approval, VOLUME 91 NUMBER 3 | march 2012 | www.nature.com/cpt

Workshop Agenda

8:15 Registration – SPPM third floor - Room 302

8:30 – 9:00 Welcome and introduction

- **Lan XUE,** Tsinghua University
- **Manuel HEITOR,** IST Portugal and IRGC Portugal
- **Kenneth OYE,** Massachusetts Institute of Technology
  Relationship between innovation and risk management by public authorities

Moderator: **Granger MORGAN**, Carnegie Mellon University

9:00 – 10:45 Session 1 – Application: Pharmaceuticals

- Introduction of the session: **Kenneth OYE,** Massachusetts Institute of Technology

- **Yi FENG**, China State Food and Drug Administration
  Title to be confirmed

- **Robyn LIM**, Health Products and Food Branch, Canada
  The Path to Adaptive Drug Regulation: A Regulator's Perspective on Balancing Benefits, Harms and Related Uncertainties in Practice

- **Thomas UNGER**, Worldwide Regulatory Strategy, Pfizer Inc.
  The Path to Adaptive Drug Regulation: An Industry Perspective

- Discussion with speakers and other experts

10:45 – 11:00 Tea Break

11:00 – 12:00 Session 2 - Application: Synthetic Biology

- Introduction of the session: **Kenneth OYE,** Massachusetts Institute of Technology

- **Todd KUIKEN,** Woodrow Wilson Center
  Managing environmental, health and security risks related to the development of synthetic biology and its applications

- **Robert CARLSON,** Biodesic
  The Pace and Diffusion of Synthetic Biology

- **Atsun GUO**, Beijing Genomics Institute
  Risk Regulation and Innovation in Synthetic Biology

- Discussion with speakers and other experts

12:00 – 12:15 Conclusion and general discussion

Speakers' Abstracts and Biographies

Lan XUE Cheung Kong Chaired Professor and Dean,
School of Public Policy and Management, Tsinghua University

Dr. Lan Xue is a Cheung Kong Chaired Professor and Dean of School of Public Policy and Management at Tsinghua University. He is also the Director of the China Institute for S&T Policy and a Deputy Director of the China Institute for Strategic Studies on Engineering and Technology Development. His teaching and research interests include public policy analysis and management, science and technology policy, and crisis management.
He also serves as an adjunct professor at Carnegie Mellon University and a Non-Resident Senior Fellow of Brookings Institution. His many public service appointments include a member of the Expert Committee on Emergency Management of the State Council of China, Vice President of China Association of Public Administration, Vice Chairman of the National Steering Committee for MPA Education, a member of the Visiting Committee for Harvard Kennedy School, and a member of the Governing Board of International Development Research Center (IDRC). He is a recipient of the Fudan Distinguished Contribution Award for Management Science.
Trained as an engineer, Prof. Xue has two master degrees in Technological Systems Management and Public Administration from State University of New York at Stony Brook. He holds a Ph.D. in Engineering and Public Policy from Carnegie Mellon University and taught as an Assistant Professor of Engineering Administration and International Affairs at the George Washington University before retuning back to China in 1996. He is also a recipient of the National Distinguished Young Scientist Award of China.

Manuel HEITOR Professor, Instituto Superior Técnico, IST Portugal
IRGC Portugal

Manuel Heitor is Full Professor at Instituto Superior Técnico, IST, the engineering school of the Technical University of Lisbon, and served as Secretary of State for Science, Technology and Higher Education in the Government of Portugal from March 2005 to June 2011.
He earned a PhD at Imperial College, London, and did post-doctoral training at the University of California San Diego in the area of experimental combustion and related energy aspects, in which he has authored several scientific papers and books.
Manuel Heitor has served as Deputy-President of Instituto Superior Técnico, Technical University of Lisbon, for the period 1993-1998 and has published several technical papers in the area of science and higher education policy. His research work includes publications in the area of the management of technology and the development of science, technology and innovation policies. Since 1995, he has been Research Fellow of the IC2 Institute, Innovation, Creativity and Capital, the University of Texas at Austin. He is co-editor of the book series on "Technology Policy and Innovation", launched through Greenwood Publishers, Connecticut and continued through Purdue University Press.
Manuel Heitor was the founding director of the IST´s "Center for Innovation, Technology and Policy Research", which was awarded in 2005 by the International Association of Management of Technology, IAMOT, has one of the top 50 global centres of research on "Management of Technology". He was co-founder in 2002 of "Globelics - the global network for the economics of learning, innovation, and competence building systems". In 2003 he was awarded with the Dibner Award of the Society for the History of Technology, SHOT.
While in the Government of Portugal, Manuel Heitor was successfully involved in attracting public and private investment on R&D, strengthening the research landscape of the country and in the reform and modernization of higher education. He was particularly instrumental in conceiving, implementing, and building up international consortia in research and advanced training with leading American universities, encompassing industry-science relationships and technology commercialization activities.

Kenneth OYE Director, MIT Program on Emerging Technologies,
Associate Professor, Political Science and Engineering System,
Massachusetts Institute of Technology (MIT)

Presentation abstract

Relationship between innovation and risk management by public authorities

An introduction on the relationship between innovation and risk management will first discuss the track record of technology forecasting and sources of errors rooted in intrinsic limits on what can be known. The challenge is to respond to the question of the opportunity of forecasting improvement though the uses of better analytic methods and of adaptive risk governance strategies to cope with forecasting failure. It is then essential to discuss what approaches to the governance of emerging technologies make sense given uncertainty over the development, diffusion and effects of technologies. This introduction will set forth principles of adaptive governance, discussing exemplary cases and cautionary tales.

Biography

Kenneth A. Oye is Director of the MIT Program on Emerging Technologies (PoET) with a joint appointment in Political Science and Engineering Systems. Prior to MIT, Professor Oye served on the faculties of Harvard University, Princeton University, the University of California, and Swarthmore College and was a guest scholar at the Brookings Institution. He holds a BA in Economics and Political Science with Highest Honors from Swarthmore College and a Ph.D in Political Science with the Chase Dissertation Prize from Harvard University.

His current research addresses issues in science and technology policy, with a focus on biotechnologies. He is a faculty researcher with the MIT Center for Biomedical Innovation and was an invited expert on the 2012 US PCAST Report to the President on Propelling Innovation in Drug Discovery, Development and Evaluation. He is a faculty PI in the NSF Synthetic Biology Engineering Research Center (SynBERC), chairs the safety committee of the International Genetically Engineered Machine competition (iGEM) and is a member of the US National Research Council Board (NRC) on Global Science and Technology.

Granger MORGAN Professor and Head, Department of Engineering and Public Policy
Carnegie Mellon University

Granger Morgan is Professor and Head of the Department of Engineering and Public Policy at Carnegie Mellon University where he is also University and Lord Chair Professor in Engineering.

He is also a Professor in the Department of Electrical and Computer Engineering and in The H. John Heinz III School of Public Policy and Management. Professor Morgan holds a BA from Harvard College (1963) where he concentrated in Physics, an MS in Astronomy and Space Science from Cornell (1965) and a Ph.D from the Department of Applied Physics and Information Sciences at the University of California at San Diego (1969). He is a member of the US National Academy of Science, a Fellow in several professional societies, and is involved in a wide variety of advisory roles.

His research addresses problems in science, technology and public policy. Much of it has involved the development and demonstration of methods to characterise and treat uncertainty in quantitative policy analysis. He works on risk analysis, management and communication; on problems in climate change and moving to a low-carbon energy system, focused particularly on electric power; on improving health, safety, and environmental regulation; and on several other topics in technology and public policy.

Yi FENG China State Food and Drug Administration

Presentation abstract

Title

Abstract

Biography
Biography

Robyn LIM Senior Science Advisor, Office of Legislative and Regulatory Modernization, Health Products and Food Branch, Health Canada

Presentation abstract
The Path to Adaptive Drug Regulation: A Regulator's Perspective on Balancing Benefits, Harms and Related Uncertainties in Practice

In recent years, a number of regulators have voiced proposals for adaptive approaches to scientifically and socially responsible drug regulation. This presentation will provide: 1) a regulatory interpretation of Adaptive Licensing concepts; 2) guiding principles regarding the balancing of benefits, harms and related uncertainties that would animate adaptive licensing strategies in practice; and 3) some considerations comparing status quo approaches on these matters and those for the future.

Biography
Robyn Lim is Senior Science Advisor with the Office of Legislative and Regulatory Modernization, Health Products and Food Branch, Health Canada, bringing technical and review-related perspectives to the development of Canada's modernized drug regulatory system since the project's inception in late 2005. In this capacity, Dr Lim developed the benefit-risk-based evidence standard and concepts for market authorisation and benefit-harm-uncertainty management for the new Canadian drug regulatory framework and has presented these and related issues at a variety of international meetings since 2007.

Prior to joining the modernization team, Dr Lim was a Health Canada clinical and non-clinical safety and effectiveness reviewer (with the Therapeutic Products Directorate, since 1996) and assessed drug submissions across product life-cycle (clinical trial applications, pre- and post-market drug submissions) and other drug issues, primarily in the fields of analgesia, anaesthesia, neurology and psychiatry. Dr Lim has participated on Health Canada intra- and inter-Directorate working groups, such as Good Review Practices (and developed TPD's Good Review Guiding Principles) and Adaptive Trial Design and at Departmental Expert Advisory Committee meetings. She was also nominated and served on the United States Pharmacopeia Neurology Expert Committee (2000-2005). Since 2007, Dr Lim has participated in a number of international public-private endeavours focussed on benefit-risk-uncertainty science. Dr Lim has received Health Canada Awards for Excellence in Risk Management (2001) and for Creativity and Innovation (2007) for her review work and as part of the modernization team, respectively. In 2012, Dr Lim also received an honour from the editors of the Journal of Pharmacoepidemiology and Drug Safety for best peer reviewer performance.

Dr Lim received Bachelor and Master's degrees from the Biochemistry Department, Queen's University at Kingston, Ontario, Canada and a Doctorate in molecular neurophysiology from the Physiological Laboratory, University of Cambridge, U.K. and Trinity College, Cambridge, U.K.

Thomas UNGER Executive Director, Worldwide Regulatory Strategy, Pfizer Inc.

Presentation abstract
The Path to Adaptive Drug Regulation: An Industry Perspective

The continued evolution of technologies, capabilities and knowledge will allow for the discovery and development of important new medicines that will improve lives of patients with unmet medical needs. Yet these same evolving factors will also impact the processes of evaluating safety, efficacy and effectiveness of therapeutics, where many experts believe they are likely to add time and complexity for both industry sponsor and regulatory decision

makers as a result of new uncertainties. Does this imply that the future for drug development will by necessity continue on a track to become more costly, lengthy and characterized by a declining willingness to innovate? Principles of adaptive decision making, a structured, iterative process of optimal decision making in the face of uncertainty, applied to drug regulation as Adaptive Licensing, may assist decision makers in more effectively responding to these evolving challenges. This presentation will consider industry perspectives and rationale of working with regulators (and payors, providers, patients and academics) to evaluate Adaptive Licensing strategies as an alternative to current models of drug regulation.

Biography

Thomas Unger is head of Business Strategy and Process Management within Pfizer's Worldwide Regulatory Strategy Group. A primary focus of his efforts has been to facilitate innovation in drug development by focusing on frameworks that improve the understanding, evaluation and communication of risk, based on the shared interests of stakeholders (companies, payors, providers, patients, and regulators) to advance new medicines that improve public health. Prior to this role, Thomas was the head of Strategy and Operations for Pfizer's new Biotherapeutics and Bioinnovation Center (BBC) Division based in South San Francisco, California. He joined Pfizer in 2005 as a member of the Strategic Management Group within Pfizer's Global Research and Development (PGRD) organization, responsible for supporting the Worldwide Development Organization Leadership Team designing and executing scientific and operational programs.

Before joining Pfizer, Thomas held a number of senior strategic advisory positions including the investment banking and venture capital firms Aperion Partners, LLC and MTM Advisors, LLC, and the management consulting firms Wood Mackenzie Limited and PA Consulting Group. Thomas started his industry career as co- founder of a number of early stage biotechnology companies including BioLogic Technologies and Miragen Incorporated.

Thomas obtained his B.S. in Biology from the University of Southern California, his Ph.D. in Biological Sciences from the California College of Medicine, University of California, Irvine, and his M.B.A. from the Marshall School of Business, University of Southern California.

Todd KUIKEN Senior Program Associate, Science and Technology Innovation Program, Synthetic Biology Project, Woodrow Wilson Centre for Scholars, USA

Presentation abstract

Managing environmental, health and security risks related to the development of synthetic biology and its applications

Over the past two years the Synthetic Biology Project at the Woodrow Wilson Center in collaboration with the Massachusetts Institute of Technology and the NSF-funded Synthetic Biology Engineering Research Center (SynBERC) have been prototyping risk assessment methods for their utility in identifying early-stage hazards and research directions for synthetic biology applications. The workshops examined the environmental effects of an E.coli-based arsenic biosensor, a cyanobacteria modified to produce sugars, a rE.coli chassis (modified genetic code chassis) and an in depth evaluation of data needs and testing methods for assessing the safety of a field release of synthetically designed algae for biofuel production. The results from these workshops will be reviewed and discussed in a broader context incorporating the iGEM (International Genetically Engineered Machines competition) safety committee protocols to provide an overview of the methods being used to manage the environmental, health and security risks related to the development of synthetic biology and its applications.

Biography

Dr. Todd Kuiken is a Senior Program Associate for the Synthetic Biology Project at the Woodrow Wilson International Center for Scholars. He is collaborating with DIYbio.org on a

project to ensure safety within the rapidly expanding community of amateur biologists. He previously worked with the Project on Emerging Nanotechnologies at the Woodrow Wilson International Center for Scholars; focusing on the environmental health and safety and public policy aspects of nanotechnology. He speaks frequently on public policy issues related to nanotechnology and synthetic biology and has published numerous articles on nanotechnology, synthetic biology, and mercury cycling.
Todd earned his Ph.D. from Tennessee Tech University where his research focused on the air/surface exchange of mercury associated with forest ecosystems. As part of his dissertation he synthesized these results with other studies associated with mercury cycling, public health threats and policy alternatives to bring attention to the threats and need for an improved public policy dealing with mercury pollution.
After completing his B.S. in Environmental Management and Technology at Rochester Institute of Technology he worked directly with renowned scientists on the biogeochemical cycling of mercury at the Oak Ridge National Laboratory. He earned an M.A. in Environmental and Resource Policy from The George Washington University concentrating on the scientific, economic and community development aspects of environmental issues. While there he worked at various environmental non-profits including the National Wildlife Federation where he worked within the Clean the Rain campaign that dealt with the environmental and public health threats associated with mercury pollution

Robert CARLSON Principal, Biodesic
Senior Lecturer, Computer Science and Engineering Department, University of Washington

Presentation abstract

The Pace and Diffusion of Synthetic Biology

Biotechnology is becoming an important economic force around the world. Revenues from genetically modified drugs, crops, and industrial products are now the equivalent of more than 2% of GDP in the U.S., and may be at more than 2.5% of GDP in China and Malaysia. The clear demand for products made using biology is encouraging ever greater governmental and private sector investment. Important targets of that investment include technologies such as synthetic biology that promise to improve production efficiencies and are leading to engineered metabolic pathways and products of ever greater complexity. Beyond the public and private sectors, students around the world are enthusiastically pushing synthetic biology, and in the process undergraduates are now demonstrating progress on projects that just a few years ago were beyond the grasp of teams of PhDs. Biotechnology is diffusing even more broadly into garages and community labs. This proliferation is seen in some quarters as beneficial due to the potential for increased innovation and job creation, while others fear negative consequences for security and safety. A historical comparison with other technologies suggests that the combination of large market demand and democratized production technologies creates a situation in which regulation and restriction leads to black markets, as has happened most recently with a variety of illicit drugs. It is an open question as to which regulatory approaches to synthetic biology will improve safety and security and which approaches will lead to greater insecurity.

Biography

Dr. Rob Carlson is a Principal at Biodesic, an engineering and consulting firm in Seattle, and is a Senior Lecturer in the Computer Science and Engineering Department at the University of Washington, where he teaches a class on developing policy and strategy in the context of rapid technological change.
At the broadest level, Rob is interested in the future role of biology as a human technology. He has worked to develop new biological technologies in both academic and commercial environments, focusing on molecular measurement and microfluidic systems. Dr. Carlson has also developed a number of new technical and economic metrics for measuring the progress of biological technologies. He is a frequent international speaker and has served

as an advisor to such diverse organizations as The Hastings Center, the PICNIC Design Festival, the UN, the OECD, the US Government, and companies ranging in size from startups to members of the Fortune 100.
Carlson is the author of the book Biology is Technology: The Promise, Peril, and New Business of Engineering Life, published in 2010 by Harvard University Press; it received the PROSE award for the Best Engineering and Technology Book of 2010 and was named to the Best Books of 2010 lists at both The Economist and Foreign Policy. Carlson earned a doctorate in Physics from Princeton University in 1997. Links to additional articles and a weblog can be found at www.synthesis.cc.

Atsun GUO Chairman, The Institutional Review Board on Bioethics and Biosafety
Beijing Genomics Institute

Presentation abstract

Risk Regulation and Innovation in Synthetic Biology

Biography

Dr. Atsun Guo, M.D., is a long time veteran in the field. Since 1980 he has done research in fields of atherosclerosis, anti-aging, and cancer in universities in both China and United States. He has joined BGI since 2011 as the chairman of The Institutional Review Board on Bioethics and Biosafety.