



**Technoscience and Regulation Research Unit
Presentation to Health Canada, Atlantic,
Tuesday October 21, 2008**

The health of Canadians is protected by policies and regulations designed to assess the safety and effectiveness of treatments, the predictive power of diagnostics, and the thoroughness of evidence on which these assessments are based. The Technoscience and Regulation Research Unit (TRRU), in the Faculty of Medicine at Dalhousie University, studies scientists, policy makers, communities, citizens, and technologies as they collectively affect the protection, treatment and prediction of the public's health. TRRU's members are engaged in a variety of projects including an analysis of the development and regulatory path of pharmaceuticals and biologics, including vaccines; the critical socio-cultural analysis of smart regulations and progressive licensing policies; the relationship between patient advocacy groups and industry funders; the role of intellectual property in the marketing of natural health products; and the incorporation of public input into the evidence base for health product evaluation. As part of our knowledge transfer activities, we are delighted to have the opportunity to present our work to Health Canada, Atlantic.



Canadian Institutes
of Health Research

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Technoscience and Regulation Research Unit (TRRU)

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Technoscience and Regulation Research Unit Biographies

Janice E. Graham, PhD (janice.graham@dal.ca)
Professor and Canada Research Chair in Bioethics
Faculty of Medicine
Dalhousie University

Janice Graham is Canada Research Chair in Bioethics and Scientific Director of the Technoscience and Regulation Research Unit (TRRU) and the Qualitative Research Commons & Studio in the Faculty of Medicine at Dalhousie University, Halifax, Canada. As a medical anthropologist, Professor Graham draws upon anthropology, science studies, technology assessment and bioethics to approach cultural, technical and moral issues in health. Interested in standardization and regulatory practices, diagnostic imaginaries, databases as cultural texts and aging, Graham's work on Alzheimer's disease and other dementia diagnostics during the 90s led to an interest in the moral basis of profit when disease is seen as a market opportunity. Her more recent ethnographic research examines safety and efficacy in the regulation of emerging biotherapeutics at Health Canada. She held a postdoctoral fellowship in geriatric medicine and neuroepidemiology (1996-8) at Dalhousie University, an endowed Research Chair in Medical Anthropology at the University of British Columbia (1998-2002), and a Canadian Institutes of Health Research New Investigator award (1999-2002). She has been a visiting senior fellow, BIOS Centre for the Study of Bioscience, Biomedicine, Biotechnology and Society, London School of Economics and Political Science, observer to Scientific and Technical meetings of the World Health Organization, and chaired the Health Canada Expert Advisory Panel on the Special Access Program. Along with several book chapters, and a forthcoming book, *Aging and Loss: Contesting the Dominant Paradigm*, University of Toronto Press, her articles have appeared in *The Lancet*, *American Journal of Epidemiology*, *Biosocieties*, *Pharmacogenetics and Genomics*, *Dementia and Geriatric Cognitive Disorders*, *Journals of Gerontology*, *Journal of Aging Studies*, *Ageing & Society*, *Philosophy*, *Psychology and Psychiatry*, *Journal of Investigative Medicine*, *Canadian Medical Association Journal*, *Lancet Neurology*, *New Genetics and Society*, *Archives of Neurology*, *Expert Opinion on Pharmacotherapy*, *Journal of Neurology*, *Neurosurgery*, and *Psychiatry*, *International Psychogeriatrics*, *Journal of Clinical Epidemiology*, and *Neuroepidemiology*. Forthcoming research explores various Health Canada axes of regulatory activities associated with the development and introduction of a new conjugate vaccine in sub-Saharan Africa, international standardization of proteomics and First Nations environmental health.

Mavis Jones (mavis.jones@dal.ca)

Mavis Jones is a political sociologist. Her areas of interest include risk governance, expertise and evidence, deliberative democracy, policy networks and policy learning - all in the context of biotechnology. She has conducted research in the UK and Canada, covering human genetics governance (genetics and insurance, gene therapy, embryology, xenotransplantation); biotechnology commissions (health and agricultural); and assisted human reproduction regulations. Her publications have dealt with such topics as comparative biotechnology governance and social shaping of technology policy. Her current research, on health technology risk regulation, is funded by a CIHR Postdoctoral Fellowship from the Institute of Genetics (Ethics, Law and Society).

Christina Holmes (cpholmes@dal.ca)

Christina Holmes is currently an Assistant Professor in the Sociology and Social Anthropology Department at Dalhousie University. Her PhD focused on how genetically modified plants (a.k.a. GMOs) are seen by the scientists who create them; how the design of and work on GMOs differs, depending on the goals and funding of the researchers; and globalization within scientific research. This research was supported by an IDRC, Canadian Window on Development Award, as well as a CIHR, Institute of Genetics, Short Term Research Grant, and a SSHRC Doctoral Fellowship. Her research interests include the anthropology of science, medical anthropology, science studies, biotechnology, and agriculture and food.

Sharon Batt (sharon.batt@dal.ca)

Sharon Batt has had a career as a writer and community activist and is currently completing an Interdisciplinary Ph.D. at Dalhousie University in Halifax, Nova Scotia under the supervision of Dr. Janice Graham. Her doctoral research is a case study of pharmaceutical funding of breast cancer groups in Canada from 1991 to 2007. She is using qualitative research methods to examine competing discourses about the ethics of these public-private alliances. She has written widely about pharmaceutical safety issues and in 2005 received the Canadian Silver Environmental Award in Environmental Health for her writing and activism on pharmaceuticals in the environment.

Elizabeth Toller (etoller@dal.ca)

Elizabeth Toller completed a combined honours degree in social anthropology and international development studies at Dalhousie University (2006) and a Masters degree at Dalhousie in Social Anthropology (2008). Her work centers on the framing of regulation as competitive advantage in the commercialization of food and health products. She uses anthropology and science studies to explore industry preparations for and responses to new regulatory interventions at Health Canada: for example, the implementation of the Natural Health Product Regulations in 2004. Elizabeth's general interests focus on policy research and analysis of cross-cutting health policy issues, including the regulation and commercialization of food and health products, and the complex relationship between government regulation and industry competitiveness in the health sector. Her work on the policy and regulation of food and health products contributes to Dr. Graham's Canadian Institute of Health Research funded project 'Risks and regulation of novel therapeutics.' She has also worked in various directorates at Health Canada, including the Bureau of Food Policy Integration and the Bureau of Chemical Safety. Liz is currently working with Health Canada's Policy, Planning, International and Administrative Affairs Directorate.

Emma Varley (emma.varley@dal.ca)

Emma Varley has received her MA in Anthropology (UBC, 2002) and her Ph.D. in Medical Anthropology (University of Toronto, 2008). Her doctoral research (2004-2005) concerned Muslim women's reproductive health amid sectarian conflict in Pakistan's Northern Areas. In 2007, Emma was Co-Investigator on a CIHR-funded study examining post-*tsunami* health service provision in southern Thailand. Since 1998, Emma has also authored and co-authored numerous policy reports during overseas consultancies, including research on behalf of SEVA Canada (Tanzania, 2002), the Aga Khan Rural Support Programme (Pakistan, 1998) and the Sustainable Development Policy Institute (Pakistan; 1999, 2004-2005, 2006). As part of her Fellowship in Bioethics, Emma is researching Muslim-Canadians' use of 'traditional' Islamic health practices and biomedical services in Atlantic Canada.

Robert Nuttall (r.nuttal@dal.ca)

Robert Nuttall is a biomedical scientist with over 10 years of experience working in medical research laboratories. For his PhD (Physiology, University of Western Ontario, 2000) he studied placenta function in relation to infertility, while for his post-doctoral training (University of East Anglia, Norwich UK; Dalhousie University, Halifax) he examined tissue loss associated with various cancers and neurodegenerative diseases. His belief that scientists have an obligation to ensure that research is done soundly, that regulation of medical therapies is done fairly, and that information is conveyed to the public accurately led him to pursue collaboration with the Technoscience and Regulation Research Unit.

Abstracts of Presentations

Janice Graham

Risks and regulation of novel therapeutic products: a case study of biologics and emerging genetic technologies

Regulation might be viewed as one of the most salient and silent mediators of science and politics. Before the products of science reach the public, they must meet regulatory standards of predictive certainty with regards to safety, efficacy and quality. Industry advocates and some portion of the public regard our present regulatory system as inefficient, charging that bureaucracy delays market access for useful products and that it thwarts research by making investment costs prohibitive. Other stakeholders argue that regulation has already become too flexible, that the cozy relationship fostered these past years between industry and government has rendered the regulatory system ineffective. This presentation is an introduction to the CIHR funded study of Health Canada's regulatory activities.

Mavis Jones

Regulatory modernization and relevant expertise

Drawing from ethnographic research within the Health Products and Food Branch, this paper presents observations and analyses of how current practices of regulatory modernization are affecting Branch practices. I will pay particular attention to the implications of evolving definitions of 'relevant' expertise for evidence-based decision making for the work of on-the-ground regulators. This talk opens for discussion the complex relationship of science and policy within risk regulation, particularly in the context of modernization – a process which is not always characterized by a clear internal logic.

Christina Holmes

Not all GMOs are equal: scientists, regulation, & Canadians

GMOs, although recognized as a group created with a particular method, are understood by genetic engineering scientists to be extremely diverse. Ethnographic research indicates that 'GMOs' describe organisms that may have different qualities and risks from each other. In assessing the safety, efficacy and quality of GMOs, Canadian health regulation focuses on the differences between GMOs, ignoring the simultaneous scientific recognition of GMO similarities and differences. While this regulatory practice is in line with the 'scientific' view of GMOs, civil society groups take umbrage at the neglect of GMOs as a risk category.

Sharon Batt

Pharma Flush: Drugs, Health Policy and the Environment

A social science perspective challenges the prevailing view of a pressing health policy issue: pharmaceutical drugs in the environment. We now know that the drugs we use and throw away contaminate the environment and harm aquatic life and birds. Human health impacts are uncertain but are potentially devastating. In this presentation I trace Health Canada's efforts to adapt its drug review and approval process to this emerging public health threat. I argue that the government's approach relies too heavily on technical solutions derived from the science of analytic chemistry. A multi-disciplinary approach would promote a cultural mindset of holistic environmental responsibility and would engage the public, as well as government and industry, in developing solutions.

Elizabeth Toller

Framing regulation as competitive advantage

The regulation and commercialization of Natural Health Products (NHPs) is a cross-cutting policy issue with social, economic and legal implications for Canadians and the health sector. Such implications are well seen by the way businesses in the health sector respond and adapt to new regulatory interventions, such as the *Natural Health Products Regulations*. This presentation focuses on the complexity of balancing public health regulation with industry competitiveness by focusing on a CV Technologies' commercialization of Canada's leading natural cold remedy COLD-fX. It shows how some actors engage in the emergent praxis of government regulation to win cross-sector competitive edge, while other, less resourceful players reposition their work around regulatory requirements to stay in business.

Emma Varley

Islamic Medicine, Muslim Patients, Policy & Service Possibilities for Health Canada (Atlantic)

Very little is known about Muslim-Canadian newcomers' use of transnational health products and 'traditional' Islamic health practices in Atlantic Canada, nor the ways these affect cultural assimilation or immigrant recidivism to other provinces. My post-doctoral research will examine the implications of such practices and products for Muslim-Canadian patients' health seeking, health outcomes and demonstrated under-use of available biomedical services. My presentation first provides an overview of the health practices and remedies typically associated with 'Islamic healing', then focuses on the importance of unapproved, web-purchased homeopathic health products for reducing the cultural dislocation incurred by immigration. Because a number of these products have been targeted by Health Canada Foreign Product Alerts, they present recognized health risks. However, their use by Muslim-Canadian patients is poorly understood by biomedical health service personnel, regional health boards and Health Canada, and therefore demands further investigation.

Sharon Batt

Pills, Pressure, Policy: Prescription Drug Policies and Pharma Funding of Breast Cancer Groups in Canada

Pharmaceutical company ('pharma') funding of community-based health and patients' groups is widespread in Canada and contested within the health activist community. Central to the debate is the question of whether patients have a right, under provincial health plans, to access any new drug that might help them, regardless of its cost. Many patients' groups argue they do, others contend that the opinions of these groups are distorted by their reliance on funding from the pharmaceutical industry. My doctoral research, a case history of breast cancer groups in Canada as they have developed over time, studies this question. Within the groups, contrasting ethical discourses have evolved from historically different experiences with drugs and their effects, pharmaceutical companies, and shifting government policies. By making visible these discourses, and their paths of influence and resistance, the research provides actors in the system with tools to understand, and perhaps resolve, the points of contestation.

Rob Nuttall

The Regulation and Post-Market Surveillance of Novel Biologic Therapeutics

Biologic therapeutics differ from conventional pharmaceuticals in both molecular and manufacturing complexity. The Biologics and Genetic Therapies Directorate (BGTD) of Health Canada are responsible for the approval biologics onto the market and into

clinical trials, as well as developing and updating policies and regulations related to this class of therapeutics. Working with data Janice Graham acquired during her participant observation period at BGTD between 2002 and 2005 I am doing an independent systematic assessment of several biologics that were under review during this time. By examining the concerns that were discussed during the review process with issues that have emerged in the post-approval period we will explore the relationship between market interests and public safety.