WHISTLEBLOWERS AND THE EXPOSURE OF CLINICAL RESEARCH MISCONDUCT

Brocher Foundation Workshop

NOVEMBER 18-20, 2015
Brocher Foundation
Hermance, Switzerland

WORKSHOP CONVENOR

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CONFIRMED SPEAKERS

Francoise Baylis, PhD
Charles Bosk, PhD
Lex Bouter, PhD
Raymond De Vries, PhD
Bernice Elger, Dr. med, Ph.D.
Carl Elliott, MD, PhD
Katharina Fierz, PhD, RPN
Valerie Junod, LLM, PhD
Trudo Lemmens, LLM, DCL
Douglas Sipp, BA
Erica Sutton, PhD
Leigh Turner, PhD

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WORKSHOP AGENDA

Wednesday, November 18, 2015

9:00 am to 9:30 am: Leigh Turner, *Welcome, Introductions, & Workshop Overview*

9:30 am to 10:25 am Presentation
Bioethics and the routinization of whistleblowing

Raymond G. De Vries, PhD, Professor of Bioethics, Sociology, & Medical Education, University of Michigan, Ann Arbor, Michigan, United States; Professor in Midwifery, Maastricht University, Maastricht, The Netherlands

10:25 am to 11:20 am Presentation
CIHR: Three Strikes and You're Out

Francoise Baylis, PhD, Professor & Canada Research Chair of Bioethics and Philosophy, Dalhousie University, Halifax, Nova Scotia, Canada

11:20 to 11:35 Break

11:35 am to 12:30 pm: Presentation
What is the role to play and the price to pay for whistleblowers?

Lex Bouter, PhD, Professor of Methodology and Integrity, Department of Epidemiology and Biostatistics, VU University Medical Center, Department of Philosophy, Faculty of Humanities, VU University, Amsterdam, The Netherlands

12:30 pm to 1:30 pm: Buffet Lunch at the Brocher Centre

1:30 pm to 2:25 pm: Presentation
Investigative Reporting and Critiques of the Storage of Newborn Blood Spots Obtained Without Explicit Parental Consent: Exposing Research Misconduct Occurring Within the Context of a Public Health Program

Erica Sutton, PhD
Postdoctoral Research Associate, Biomedical Ethics Program, Mayo Clinic Rochester, Minnesota, United States

2:25 pm to 3:20 pm: Presentation
Whistleblowing as part of human right to freedom of speech: scope and limits

Valerie Junod, LLM, PhD, Professor, Faculty of Law, University of Geneva Geneva, Switzerland

3:20 pm to 3:35 pm: Break

3:35 to 4:30 pm: Presentation
Why Did No One Pay Attention to the Whistleblower?: The Case of Preoperative Beta Blockers

Charles L. Bosk, PhD, Professor of Sociology, Professor of Anesthesiology & Critical Care, Senior Fellow, Leonard Davis Institute of Health Economics, University of Pennsylvania, Philadelphia, Pennsylvania, United States

4:30 to 5:15 pm: *General Discussion Following Today's Presentations*

7:00 pm Dinner at the Villa Brocher

Thursday, November 19, 2015

9:15 am to 9:30 am: Leigh Turner, *Welcome and Introduction*

9:30 am to 10:25 am: Presentation
Psychiatric Research Misconduct and Whistleblowing at the University of Minnesota

Carl Elliott, MD, PhD, Professor, Center for Bioethics & Department of Philosophy University of Minnesota, Minneapolis, Minnesota, United States

10:25 am to 11:20 am: Presentation
Reflections of a Side-Line Whistleblower

Trudo Lemmens, LLM, DCL, Associate Professor and Scholl Chair in Health Law & Policy, University of Toronto, Toronto, Ontario, Canada

11:20 to 11:35 Break

11:35 am to 12:30 pm: Presentation
Scientific Misconduct, Soil on Which it Flourishes and Remedies

Katharina Fierz, PhD, RPN, Scientific Collaborator, Institute of Nursing Science, University of Basel

12:30 pm to 1:30 pm: Buffet Lunch at the Brocher Centre

1:30 pm to 2:25 pm: Presentation
Scientific Whistleblowing in Japan

Douglas Sipp, BA, Research Specialist RIKEN Center for Developmental Biology, Kobe, Japan; Project Professor, Keio University School of Medicine, Tokyo, Japan

2:25 pm to 3:20 pm: Presentation
Blowing the Whistle on Non-compliant "Patient-funded Stem Cell Research"

Leigh Turner, PhD, Associate Professor, Center for Bioethics & School of Public Health, University of Minnesota, Minneapolis, Minnesota, United States

3:20 pm to 3:35 pm: Break

3:35 to 4:45 pm: Discussion

7:00 pm Dinner at the Villa Brocher

Friday, November 20, 2015

9:15 am to 9:30 am: Leigh Turner, *Welcome and Introduction*

9:30 am to 10:25 am: Presentation
Whistle-blowing protection in the context scientific misconduct at academic institutions

Bernice Elger, Dr. med, PhD, Dipl. Theol., Professor and Director, Unit for Health Law, Ethics and Humanitarian Medicine Center for Legal Medicine, University of Geneva, Geneva, Switzerland

10:25 am to 11:00: *Discussion: Projects, Plans, & Possibilities*

11:00-11:15 am: Break

11:15-12:00 *Discussion: Projects, Plans, & Possibilities* (Continued)

12:00-1:00 Buffet Lunch at the Brocher Centre & *Conclusion to the Workshop*

Note to Invited Speakers: Some of you might need to leave Brocher before 1:00 pm in order to reach the airport or train station in time for your trip home. Please feel welcome to leave at whatever time you have to depart. We do not have room reservations at the Brocher Foundation for the evening of Friday, November 20th.

SPEAKERS AND PRESENTATION TOPICS

Francoise Baylis, PhD

Professor & Canada Research Chair of Bioethics and Philosophy
Dalhousie University
Halifax, Nova Scotia, Canada

Presentation: CIHR: Three Strikes and You're Out

In this presentation I want to look at the profile of the classic whistleblower and compare this with the profile of the gadfly. The question I am interested in is whether one or the other – the whistleblower or the gadfly – is at greater risk of being effectively marginalized/neutralized by the powerful.

The classic whistleblower is a person with access to privileged information (usually an employee with deemed duties of loyalty and confidentiality) who, in pursuit of the common good, exposes some ethical wrongdoing in the hope/expectation of forcing the wrongdoer to both make amends and change her ways. Classic cases of whistleblowing typically involve violations of such basic ethical rules as: "don't lie", "don't steal", "don't cheat". For many (but not all) whistleblowers, the act of whistleblowing comes at the end of a long road with other efforts to redress the situation having failed (sometimes miserably).

The gadfly, on the other hand, is a person who through persistent pointed comments and questions attempts to goad the wrongdoer into changing her ways – the goading may be public or private. Typically, the gadfly is not so much involved in the disclosure of privileged information about lying, stealing, cheating or the like, though in specific cases there may well be the threat of revelations. Indeed, the gadfly may become a whistleblower.

Whistleblowers and gadflies have much in common. Most importantly, both are modern day upstanders -- they are persons who stand up for their beliefs even when required to do so alone. Both act on their conscience from a point of principle in challenging the status quo (which typically entails challenging authority). Neither does so in pursuit of power or with the expectation of praise. I will explore these roles with reference to a series of recent experiences with the Canadian Institutes of Health Research (CIHR).

Biography

Francoise Baylis holds the Canada Research Chair in Bioethics and Philosophy. Her research aims to move the limits of mainstream bioethics and develop more effective ways to understand and tackle public policy challenges in Canada and abroad. Her extensive publication record spans many topics, including research involving children, the role of bioethics consultants, women's health, human embryo

research, and novel genetic technologies. Her work challenges readers to think broadly and deeply about the direction of health, science and biotechnology. Her most recent book with Carolyn McLeod is *Family-making: Contemporary ethical challenges (2014).* Her next book with Angela Ballantyne is *Clinical research involving pregnant women: Missed Trials (2016).*

Charles L. Bosk, PhD

Professor of Sociology,
Professor of Anesthesiology & Critical Care
Senior Fellow, Leonard Davis Institute of Health Economics
University of Pennsylvania
Philadelphia, Pennsylvania, United States

Presentation: Why Did No One Pay Attention to the Whistleblower?: The Case of Preoperative Beta Blockers

Drawing attention to outrageous research misconduct is rarely welcomed or rewarded. Whistle blowers have their backgrounds scrutinized, their sanity questioned, and their loyalties and honor impugned. They become organizational pariahs. No organization rushes to employ whistleblowers for obvious reasons. The fact that it takes outrageous research misconduct of which they somehow become aware to motivate a whistle blower has the defect that it limits our understanding outrageous research misconduct to the known knowns. In this paper, I would like to call attention to another category of outrageous research misconduct: the seen and excused normal errors that occur when the randomized clinical trial trumps common sense.

Research misconduct that is normal, outrageous, but almost never subject to whistle blowing has a number of characteristics. First, normal and outrageous research misconduct is excused as an example of the self-correcting nature of science, a reason for celebration rather than despair. Normal but outrageous research misconduct exemplifies how forgiving social institutions are of their embedded failures.

Normal but outrageous misconduct typically involves flawed decision-making that spans multiple levels of social organizations. With normal and outrageous misconduct, the decision-making at each level of social organization is both independent and unaware of the normal but outrageous misconduct at the prior level of social organization; each act of outrageous misconduct enables the next; and any dissenting voices are subject to a 'disqualification heuristic.

I will use the case of the adoption and abandonment of pre-operative beta-blockers to examine how normal but outrageous misconduct occurs, how it goes unnoticed, and how those who are accountable for outrageously flawed decision-making evade responsibility. In the case of pre-operative beta blockers outrageous misconduct by an IRB lead to publication of a randomized clinical trial on the efficacy of using preoperative beta blockers to prevent myocardial infarction in the *New England Journal of Medicine* despite the fact that the analysis of the trial data was faulty; how the publication of that flawed trial led to the improper adoption of an evidence-base guideline that proved to do more harm than good; and how the enthusiasm for pre-operative beta blockers is a case of misconduct that unfolded slowly over time,

involved the failure of multiple gatekeepers—all of whom failed to pay attention to the voices urging a more cautious approach. Finally, this paper asks: what can be done to reduce outrageous misconduct that becomes normalized and neutralized as a 'natural' part of the process of clinical research.

Biography

Charles L. Bosk is professor of sociology and anesthesiology and critical care at the University of Pennsylvania. He is a fellow of The Hastings Center and in 2013 was recipient of the Leo G. Reeder Award from Medical Sociology Section of the American Sociological Association for distinguished contributions to Medical Sociology. He was elected to the Institute of Medicine in 2013. He is the author of *Forgive and Remember* (University of Chicago Press, 2nd edition 2003) and *All God's Mistakes: Genetic Counseling in a Pediatric Hospital* (University Of Chicago Press, 1992). His most recent book, *What Would You Do? Juggling Bioethics and Ethnography* (University of Chicago Press 2006), is a series of case studies that explore how moral authority is constructed and legitimated in American society, and how that authority influences the choice of which issues are put on the public agenda, and which solutions receive consideration as "reasonable."

Lex Bouter, PhD

Professor of Methodology and Integrity
Department of Epidemiology and Biostatistics, VU University Medical Center
Department of Philosophy, Faculty of Humanities, VU University
Amsterdam, The Netherlands

Presentation: What is the role to play and the price to pay for whistle-blowers?

While responsible conduct of research is clearly the norm, breaches of the principles listed in the authoritative codes of conduct occur and some of these may be alarmingly common. In fact there is a whole spectrum of minor and major research misbehaviors. At the extreme end of the spectrum there are clear instances of research misconduct, like fabrication, falsification and plagiarism. These major forms of misbehavior are clearly wrong, and are typically committed intentionally or are due to gross neglect. Between responsible conduct of research and research misconduct there is a large zone of questionable research practices, which may do much damage on the aggregate level because of its high prevalence. These minor forms of misbehavior may be committed intentionally or unintentionally. In the latter case scientists do not know or do not agree that the behavior at issue should be avoided.

Looking back at high profile cases of research misconduct it seems clear that whistle-blowers typically prompt the start of the investigations. One may wonder whether whistle-blowers also have a role to play in the diagnosis of questionable research practices. Although whistle-blower protection schemes are usually in place, these brave colleagues often suffer from serious negative consequences from their actions. For that reason anonymous whistle-blowing can be considered. But a serious drawback of making anonymous allegations eligible is that it becomes more easy to make false accusations and get away with it.

The presentation will focus on three related issues: 1) Should whistle-blowers restrict themselves to suspicions of research misconduct or also report questionable research practices?; 2) Is anonymous whistleblowing acceptable?; 3) How can false accusations be identified before they do damage?

Biography

Lex Bouter was born in Rotterdam in 1956. After obtaining a MSc degree in Medical Biology at Utrecht University in 1982, he lectured at teacher training colleges in Tilburg and Utrecht. In 1984 he joined Maastricht University, where he was trained as an epidemiologist and obtained his PhD. In 1988 he published a Dutch textbook on epidemiology, the seventh revised edition of which will appear in 2015.

In 1992 Bouter took up a tenured position as Professor of Epidemiology and Scientific Director of the EMGO+ Institute for Health and Care Research at the VU

University Medical Center in Amsterdam. He was Editor (1996-2002) and Editor-in-Chief (2002-2006) of the Cochrane Collaboration Back Review Group.

From 2001 until 2006 he additionally chaired of one of the six divisions at the VU University Medical Center. He was president of the Netherlands Epidemiological Society (1996-1997), member of the Health Council of the Netherlands (2001-2013), vice-chair and methodologist of the Dutch Central Committee on Research involving Human Subjects (2001-2013), and chair of the program committee of the Innovative Medical Devices Initiative of the Netherlands Organization for Scientific Research (since 2009).

From 2006 until 2013 he was Rector Magnificus and member of the Executive Board of VU University Amsterdam. In this function he focused on combining research groups in interdisciplinary research institutes. Also as rector Lex pleaded for attention for the societal impact of research. And for attention for the dilemmas around scientific integrity.

Subsequently Lex prepared for a return to science during a sabbatical leave. In 2014 his tenured professorship was broadened to Methodology and Integrity. He is currently involved in teaching and research regarding responsible conduct of research, questionable research practices and research misconduct.

Lex Bouter is author or co-author of 665 scientific publications contained in the Web of Knowledge, which have been cited more than 39,500 times (WoK h-index of 105). He is listed among the 400 most influential biomedical researchers and has supervised 73 PhD students, of whom to date 14 became full professor.

Raymond G. De Vries, PhD

Professor of Bioethics, Sociology, & Medical Education, University of Michigan
Ann Arbor, Michigan, United States
Professor in Midwifery, Maastricht University,
Maastricht, The Netherlands

Presentation: Bioethics and the routinization of whistleblowing

Whistleblowing has a long and curious relationship to the contemporary practice of bioethics. Some historians of bioethics assert that whistleblowing is responsible for the current incarnation of ethics in medicine. Rothman (1991), for example, claims American bioethics "began with a whistleblower and a scandal", a reference to Dr. Henry Beecher, a scientist who created a scandal in the field of medical research in 1966 when the *New England Journal of Medicine* published his article, "Ethics and Clinical Research," an exposé of the abuse of human subjects. This may well be true, but whistleblowing by its very definition resists institutionalization. Bioethics quickly became a routine part of medical education, clinical practice, and research, developing ways to respond to solve and explain away the ethical problems of medicine. In this presentation I explore the process by which bioethics routinized whistleblowing, ironically making whistleblowing more complicated and dangerous to the whistleblower. I conclude with a call for a more critical and reflexive bioethics that is willing to expose the failures of medicine, both personal and structural.

Biography

Raymond De Vries is Professor at CAPHRI School for Public Health and Primary Care at Maastricht University, the Netherlands and co-Director, Center for Bioethics and Social Sciences in Medicine (cbssm.org), at the University of Michigan. He is the author of *A Pleasing Birth: Midwifery and Maternity Care in the Netherlands* (Temple University Press, 2005), and co-editor of *The View from Here: Bioethics and the Social Sciences* (Blackwell, 2007) and *Qualitative Methods in Health Research* (Sage, 2010). He is co-editor of a special issue of *Social Science and Medicine* (2013) that examines how bioethics is shaped by social and cultural forces, and, together with Libby Bogdan Lovis and Charlotte De Vries, co-edited a special issue of the *Journal of Clinical Ethics* (2013) on the ethics of choice of place of birth. His current research explores ethical issues in biobanking and precision medicine and the problems with the export of western bioethical ideas and principles to non-western cultures.

Bernice Elger, Dr. med, PhD, Dipl. Theol.

Professor and Director, Unit for Health Law, Ethics and Humanitarian Medicine
Center for Legal Medicine, University of Geneva
Geneva, Switzerland

Presentation: Whistle-blowing protection in the context scientific misconduct at academic institutions

Protection of whistleblowers is mentioned in the Integrity guidelines of some Swiss universities, for example in the rules of the University of Basel. However, it is not explained how such protection would take place. Indeed, the procedures in many Swiss universities, as well as at the Swiss National Science Foundation imply often, that anonymity - the most powerful protection - cannot be granted. In this presentation, we will present the Swiss guidelines that mention whistle blower protection. Individual anonymised cases will be discussed in order to illustrate the shortcomings of the existing university regulations. The aim of the presentation is to explain, based on information about several real cases, which type of whistle blower protection would be needed. It will be shown that in order to be effective, whistle blower protection needs to be embedded in a number of additional measures to prevent or investigate true or alledged cases of integrity violations. The presentation will also briefly introduce a qualitative research project that is about to start at the Universities of Basel and Geneva in this area.

Biography

Prof. Bernice Elger, studied medicine and theology in Germany, France, Switzerland and the US and obtained a specialty degree in internal medicine. She is the head of the Unit for health law, ethics and humanitarian medicine, Center for legal medicine, University of Geneva, Switzerland, as well as affiliated with the Institute for Biomedical Ethics, University of Basel, and obtained several awards for her work, including the Bizot Award for her work on biobanks (2005) and the Swiss Research Award in Primary Care (2010).

Carl Elliott, MD, PhD

Professor, Center for Bioethics & Department of Philosophy
University of Minnesota
Minneapolis, Minnesota, United States

Presentation: Psychiatric Research Misconduct and Whistleblowing at the University of Minnesota

In March 2015, after a number of public scandals, including five years of sustained protest over the suicide of an involuntarily committed research subject in an industry-funded antipsychotic study, the University of Minnesota finally suspended enrollment in drug studies in its Department of Psychiatry. In this presentation I will outline the ways in which university officials fought efforts to scrutinize its research practices, the tactics that whistleblowers and activists used to fight back, and the forces that eventually produced some transparency and reform at the university, however limited.

Biography

Carl Elliott MD PhD is Professor in the Center for Bioethics at the University of Minnesota. He is the author or editor of seven books, including *White Coat, Black Hat: Adventures on the Dark Side of Medicine* (Beacon, 2010) and *Better than Well: American Medicine Meets the American Dream* (Norton, 2003.) His articles have appeared in *The New Yorker*, *The Atlantic Monthly, The London Review of Books, Mother Jones, The New York Times* and *The New England Journal of Medicine.* He has been a Network Fellow at the Safra Center for Ethics at Harvard University, Visiting Associate Professor at the Institute for Advanced Study in Princeton, New Jersey, and a William Evans Fellow at the University of Otago in New Zealand. He is a Fellow of the Hastings Center, an Honorary Member of the Caribbean Bioethics Society, and a recipient of the Erikson Prize for Excellence in Mental Health Media.

Katharina Fierz, PhD, RPN

Scientific Collaborator, Institute of Nursing Science, University of Basel

Presentation: Scientific misconduct, soil on which it flourishes and remedies

Scientific misconduct generally becomes a topic in case of a respective finding; an offender is often seen as a 'bad apple' and once the offender has been removed from the scene, life goes on as before. Scientific misconduct, however, must be seen from a system perspective, and so are suggested remedies. Moreover, defining what is scientific misconduct and what is not is always – with few exceptions – difficult and a matter of ongoing discourse.

Biography

Katharina Fierz, originally a psychiatric and mental health nurse, finished her Master's degree at the University of Basel in 2003 and defended her PhD in 2012. Although not her research topic, throughout her career, scientific misconduct and good scientific conduct have been one of her main interests and teaching contents.

Valerie Junod, LLM, JSM, PhD

Professor, Faculty of Law, University of Geneva
Professor, Faculty of Law, University of Lausanne
Geneva, Switzerland

Presentation: Whistleblowing as part of human right to freedom of speech: scope and limits

The European Court of Human Rights recognizes that freedom of speech encompasses the right to criticize one's employer, and - under strict conditions - the right "to go public" with these criticisms. However, the conditions that the employee must fulfill in order to benefit from this legal protection are quite strict. Moreover, if ultimately a court confirms that these conditions are indeed met and that the employer did dismiss the employee unfairly, the scope of protection remains limited. Most of the time, the employee is only entitled to moderate pecuniary damages, but will not be reintegrated in his or her job.
Several cases decided by the European Court of Human Rights illustrate the limits of the protection granted under Article 10 of the European Convention on Human Rights. *Guja v. Moldova* (2008), *Heinisch v. Germany* (2011) and *Gillberg v. Sweden* (2012) are prominent examples.

Biography

After a J.D. from the University of Geneva Law School, Valerie Junod studied at the University of Pennsylvania (LL.M.) and at Stanford University (J.S.M.). Her PhD thesis at the Geneva law school was on drug clinical trials; the book was awarded the Walter Hug, the Joseph des arts and the Latsis prizes.

Valerie Junod's areas of expertise are pharmaceutical regulations (from intellectual property to advertising, including marketing authorization and price reimbursement) and health law (reproductive medicine, genetic analyses, transplantation). She is also interested in issues related to conflicts of interest, freedom of speech, freedom of information, and whistleblowing.

Valerie Junod is a professor of law at both the University of Geneva and the University of Lausanne, where she teaches pharmaceutical law, biotech law, innovation law and contract law. She is also a lawyer admitted to the bar and counsel at a Geneva law firm.

Since 2014, she is a member of the Swiss national bioethics commission.

Trudo Lemmens, LLM, DCL

Associate Professor and Scholl Chair in Health Law & Policy
University of Toronto
Toronto, Ontario, Canada

Presentation: Reflections of a Side-Line Whistleblower

I have been a witness to and, at different levels, been involved in five significant academic controversies. As a young academic, I testified about what I perceived as academic malpractices. At my current university, I publically commented on two well-known controversies, and explicitly supported two well-known academics at the centre of controversies at the interface of academia-industry relations. I have also provided advice to other colleagues, particularly in medicine, about difficulties they encountered in their employment context. I have supported and continue to support actively, albeit from a distance, colleagues at the University of Minnesota in their struggle to expose problematic research practices in their University. And I have chaired a panel of an academic Committee of Inquiry into a research controversy in a Canadian university. In my presentation, I will reflect on some of my experiences with these controversies. I will elaborate on three different aspects. I will say something about what I see as the shared personal characteristics of several whistleblowers I have encountered, both their virtues and (for some critics) their vices. This may help us think about whether and to what extent we should expect others to follow their lead and what we may need to facilitate whistleblowing. I will then say something about the practice of supporting whistleblowers, the consequences it can entail, and the dilemmas one can face in doing so. Finally, I will comment on the type of advice I now tend to give to people in different stages of their career with respect to possible whistle-blowing, and how I think we may improve a culture of critical reflection in academia.

Biography

Trudo Lemmens is Professor and Scholl Chair in Health Law and Policy at the Faculty of Law of the University of Toronto (with cross-appointments in the Faculties of Public Health and Medicine, and the Joint Centre for Bioethics). He has been a visitor at and member of other institutions, including the Institute for Advanced Study in Princeton, the Center for Transnational Legal Studies (London, UK), the KULeuven, the University of Otago, Torcuato di Tella University (Buenos Aires), St. Anne's College Oxford, and the HeLEX Center for Health, Law and Emerging Technologies. In addition to books and chapters, his articles on a variety of health law and bioethics related topics appeared in leading law, policy, science and bioethics journals. He recently was a member of an expert panel of the Council of Canadian Academies on data sharing in the context of health research, and he sits on the Advisory Committee on Health Research of the Pan American health Organization and on the Board of the Ontario Mental Health Foundation. Professor Lemmens has appeared as expert before committees of the Canadian Senate and

House of Commons and has participated in advisory committees for provincial, national and international organizations, including the World Health Organization. At the University of Toronto, he currently teaches courses on Health Law and Bioethics, Pharmaceutical Governance, and Research Ethics. His research focuses on the role of law in dealing with legal, ethical and social issues of health care technologies, particularly in the area of pharmaceuticals, and on legal and ethical issues of biomedical research.

Douglas Sipp, BA
Research Specialist, RIKEN Center for Developmental Biology, Kobe, Japan
Project Professor, Keio University School of Medicine, Tokyo, Japan

Presentation: Scientific whistleblowing in Japan

Features of the social and legal systems in Japan, such as strongly reinforced group loyalty, cultural emphasis on honor and shame over morality and guilt, and a legal regime in which civil and criminal defamation laws favor plaintiffs and do not privilege factually true statements, make whistleblowing (*naibu kokuhatsu*, lit. 'internal accusation') a fraught and risky affair. For scientists, the hierarchical, insular academic/research career path and the close-knit, opaque personal networks that inform hiring and funding decisions are powerful disincentives against insider revelations, particularly by junior staff in precarious positions, and the weak support system for whistleblowers has resulted in most whistleblowing being undertaken by anonymous persons, many of whom rely on information technology to conceal their identities and reach wide audiences. In this talk, I will describe a number of recent whistle blowing cases, and discuss how the impact that the lack of a 'whistleblowing culture' has on the sciences in Japan.

Biography

Douglas Sipp is a research specialist focusing on science and regulatory policy at the RIKEN Center for Developmental Biology (CDB). He graduated from Rutgers University with a degree in English Literature in 1991. After working in the software and publishing industries, he joined the CDB as head of the communications office in 2002. From 2009 to 2014, he led a research unit studying policy and ethics issues in the translation and commercialization of stem cell research. He has published more than 45 research papers, reviews, and book chapters, presented his work more than 100 international meetings, and has been extensively interviewed by the international scientific and mass media. He has served on task forces addressing the problem of the marketing of unproven stem cell treatments for both the International Society of Stem Cell Research and the International Society for Cell Therapy, as well as numerous international scientific committees.

Erica Sutton, PhD
Postdoctoral Research Associate, Bioethics Program, Mayo Clinic
Rochester, Minnesota, United States

Presentation: Investigative Reporting and Critiques of the Storage of Newborn Blood Spots Obtained without Explicit Parental Consent: Exposing Research Misconduct Occurring Within the Context of a Public Health Program

Newborn screening is a public health program that uses heel prick blood draws to screen infants days after birth for a series of rare congenital health conditions. In many jurisdictions these newborn blood spots are stored for possible future use not only for the health of individual children, but also for research purposes. Historically, both screening and storage have occurred largely without parent knowledge and/or explicit parental consent. In an empirical, Ontario-based case study, I explored stakeholder rationales regarding the decision to store newborn blood spots without explicit, informed, parental consent as part of Newborn Screening Ontario. This implied consent approach to screening and storage, while common, has resulted in considerable disagreement, and, in some cases, public outrage at the undisclosed storage of newborn blood spots and their subsequent use in forensic databases and other controversial data banks. In this presentation I will review the pathways by which the storage of newborn blood spots became known to parents and the general public, subsequent reactions by parents and other parties, and the institutional reforms and health policy changes that have occurred after such databases became matter of public knowledge. I will pay particular attention to the role of investigative reporters in disclosing, describing, and critiquing practices of obtaining, screening, and storing blood spots that do not involve voluntary informed consent from parents of newborns.

Biography

Erica Sutton is a postdoctoral research fellow at Mayo Clinic's Biomedical Ethics Program. She is an interdisciplinary social scientist engaged in social and behavioral science research that explores the health care experiences of individuals living with rare genetic conditions; the manner in which biotechnologies shape personal experience and social life; and the ethical implications of these technologies for individuals, public health, social policy, health care institutions, and communities. She earned her PhD in public health and bioethics at the Dalla Lana School of Public Health and the Joint Centre for Bioethics at the University of Toronto.

Leigh Turner, PhD

Associate Professor, Center for Bioethics & School of Public Health
University of Minnesota
Minneapolis, Minnesota, United States

Presentation: Blowing the Whistle on Non-compliant "Patient-funded Stem Cell Research" in the U.S.

Clinics marketing unproven and unlicensed stem cell interventions are proliferating across the United States. Such businesses appear to cluster in Arizona, California, Florida, Nevada, and Texas, though they are not confined to the southern U.S. While some of these companies market unproven and unapproved stem cell procedures as putative "therapies" provided outside the context of clinical trials, other businesses charge thousands or tens of thousands of dollars for access to what they describe as "patient-funded clinical studies." In numerous instances, such trials have not been submitted to the FDA for review. Rather, the FDA has initiated clinical studies of "stem cells" without independent review or following institutional review board alone instead of after both IRB approval and review. In my presentation I will examine several cases in which whistleblowers and other critics have been threated by U.S. businesses conducting such studies. I will explore the steps whistleblowers and other concerned parties took to draw public scrutiny to what they perceived as unethical and noncompliant stem cell studies, the tactics companies used in an attempt to intimidate and silence critics, and the aftermath of such confrontations. In particular, I will explore how businesses that appear to violate federal laws governing the manufacture and administration of stem cells use the threat of litigation and other tools of intimidation as cudgels against whistleblowers.

Biography

Leigh Turner is an Associate Professor at the University of Minnesota's Center for Bioethics, College of Pharmacy, and School of Public Health. Before relocating to Minnesota Turner was an Associate Professor and William Dawson Scholar in the Biomedical Ethics Unit and Department of Social Studies of Medicine at McGill University. Turner is co-editor of *Risks and Challenges in Medical Tourism: Understanding the Global Market for Health Services* and *The View from Here: Bioethics and the Social Sciences*. He is the author of numerous publications examining ethical and social issues related to transnational medical travel and globalization of health care. Turner's current research programme addresses ethical, legal, and regulatory concerns associated with domestic and international clinics marketing unproven cell-based interventions.