

Profile  
 (List of Publications)  
 September 24, 2015

## TRUDO LEMMENS LIST OF PUBLICATIONS

### 1. Refereed publications

#### A. Articles and Invited Editorials

1. Shannon Gibson, Hamid Raziee & Trudo Lemmens, “Why the Shift? Taking a Closer Look at the Growing Interest in Niche Markets and Personalized Medicine” (2015) 7(1) *World Medical & Health Policy* 3-27.
2. Trudo Lemmens & Shannon Gibson, “Decreasing the Data Deficit: Improving Post-Market Surveillance in Pharmaceutical Regulation” (2015) 59(4) *McGill Law Journal* 943-988.
3. Shannon Gibson & Trudo Lemmens, “The Promise and Peril of Adapting the Regulatory System to the Pharmacogenomic Context” (2015) 8(2) *McGill J. Law & Health* S145-230.
4. Shannon Gibson & Trudo Lemmens, “Niche Markets and Evidence Assessment in Transition: A Critical Review of Proposed Drug Regulatory Reforms” (2014) 22(2) *Medical Law Review* 200-220
5. Roberto Abadie, Jonathan Kimmelman, Josiane Lafleur & Trudo Lemmens, “Recall of Consent to Invasive Research Procedures: A Pilot Investigation” (2014) (May/June) *IRB: Ethics and Human Research* 1-7
6. Nav Persaud, Thom Ringer & Trudo Lemmens, “How Can Journals Respond to Threats of Libel Litigation?” (2014) 11(3) *PLoS Medicine* e1001615 1-4
7. Ruth Macklin *et al.*, “The OHRP and Support—Another View” (2013) 369: *New England Journal of Medicine* e3 (peer-reviewed joint letter to the editor, signed by 45 scholars, drafted by 3 lead authors (Ruth Macklin, Lois Shepherd & Alice Dreger).
8. Colleen Flood and Trudo Lemmens, “Introduction: Global Health Challenges and the Law” (2013) 41(1) *Journal of Law, Medicine and Ethics* 9-15.
9. Trudo Lemmens, “Pharmaceutical Knowledge Governance: A Human Rights Perspective” (2013) 41(1) *Journal of Law, Medicine and Ethics* 163-84.

10. Trudo Lemmens & Candice Telfer, "Access to Information and the Right to Health: The Human Rights Case for Clinical Trials Transparency" (2012) 31(1) *American Journal of Law & Medicine* 63-112.
11. Jonathan Kimmelman, Trudo Lemmens & Scott Y.H. Kim, "Analysis of Consent Validity For Invasive, Nondiagnostic Research Procedures" (2012) 34(5) *IRB: Ethics and Human Research* 1-7.
12. Simon Stern & Trudo Lemmens, "Legal Remedies for Medical Ghostwriting: Imposing Fraud Liability on Guest Authors of Ghostwritten Articles" (2011) 8(8) *PLoS Medicine* 1-8 (online: <http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001070>). (reprinted in: (2103) 22(4) *Medical Writing* (online: <http://medicalwriting.emwa.org/article/show/pdf/953/>).
11. Karmela Krleza-Jeric, Trudo Lemmens, Ludovic Reveiz, Luis-Gabriel Cuervo & Lisa Bero, "Prospective registration of protocol and results disclosure of clinical trials in the Americas; international standards, their implementation, and proposals for further development" (2011) 30(1) *Pan American Journal of Public Health* 87-96. (online: [http://issuu.com/researchforhealth/docs/2011\\_ictip\\_americas](http://issuu.com/researchforhealth/docs/2011_ictip_americas)). Also in Spanish: "Registro prospectivo y comunicación de los resultados de los ensayos clínicos en la Región de las Américas" (2011) 30(1) *Revisita Panamericana de Salud Publica* 87-96.
12. Lori Ferris & Trudo Lemmens, "Governance of Conflict of Interest in Postmarketing Surveillance Research and the Canadian Drug Safety and Effectiveness Network" (2010) 4(2) *Open Medicine* (online: <http://www.openmedicine.ca/article/view/371/338>).
13. Trudo Lemmens, Daryl Pullman & Rebecca Rodal, "Revisiting Genetic Discrimination Issues in 2010: Policy Options for Canada" Peer reviewed Policy Brief, Genome Canada 2010 (online: <http://www.genomecanada.ca/en/ge3ls/policy-portal/directions.aspx>).
14. Daryl Pullman & Trudo Lemmens, "Keeping the GINA in the bottle: assessing the current need for genetic non-discrimination legislation in Canada (2010) 4(2) *Open Medicine* E95-E.97 (online: <http://www.openmedicine.ca/article/view/339/321>).
15. Karmela Krleza-Jeric & Trudo Lemmens, "The 7<sup>th</sup> revision of the Declaration of Helsinki: good news for the transparency of clinical trials" (2009) 50 *Croatian Medical Journal* 105-110.
16. Michael D.E. Goodyear, Trudo Lemmens, Dominique Sprumont & Godfrey Tangwa, "Does the FDA possess the authority to trump the Declaration of Helsinki?" (2009) 338 *British Medical Journal* 1157-1158 (invited editorial).

17. Tom Archibald and Trudo Lemmens, "Data Collection from Legally Incompetent Subjects: A Paradigm Legal and Ethical Challenge for Population Databases" (2008, Special Edition: Visions) *Health Law Journal* 145-192.
18. Timothy Caulfield, *et al.* "Research Ethics Recommendations for Whole-Genome Research: Consensus Statement" (2008) 3 (e73) *PLoS Biology* 0430-0435.
19. Ron Bouchard & Trudo Lemmens, "Privatizing Biomedical Research: A "Third Way"?" (2008) 26 *Nature Biotechnology* 31-36.
20. Michael D.E. Goodyear, Karmela Krleza-Jeric and Trudo Lemmens, "The Declaration of Helsinki: Mosaic Tablet, Dynamic Document, or Dinosaur?" (Invited Editorial) (2007) 336 *British Medical Journal* 624-625.
21. Trudo Lemmens and Paul B. Miller, "Regulating the Market in Human Research Participants" (2006) 3(8) *PLoS Medicine* 1238-1241. (online: <http://www.plosmedicine.org/article/fetchObject.action?uri=info%3Adoi%2F10.1371%2Fjournal.pmed.0030330&representation=PDF>)
22. Ezekiel Emanuel, Trudo Lemmens and Carl Elliott "Should society allow research ethics boards to be run as for-profit enterprise (2006) 3(7) *PLoS Medicine* e309: 0941-0944. And: Trudo Lemmens and Carl Elliott "Research ethics boards: reply from Trudo Lemmens and Carl Elliott" (2006) 3(10) *PLoS Medicine* e471 (letter to the editor). (online: <http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.0030309>).  
Also published in Spanish: "¿Debería la sociedad permitir que los Comités de Ética para la Investigación sean manejados como empresas con fines lucrativos?" (2007) 10(1) *Boletinas Fármacos* (translated by Ethel Martínez).
23. Raymond Devries and Trudo Lemmens, "Evidence Subjugated: The Social and Cultural Shaping of Medical Facts" (2006) 62(11) *Social Science & Medicine* 2694-26706.
24. Trudo Lemmens, "Federal Regulation of REB Review of Clinical Trials: A Modest but Easy Step Towards an Accountable REB Review Structure in Canada" (2005) 13(2-3) *Health Law Review* (Special Issue on Research Governance, M. McDonald, ed.) 39-50. (peer-reviewed special issue)
25. Trudo Lemmens, "Leopards in the Temple: Restoring Integrity to the Commercialized Research Scene" (2004) 32(4) *Journal of Law, Medicine and Ethics* 641-657.
26. Trudo Lemmens, "Can Insurance Law Accommodate the Uncertainty Associated with Preliminary Genetic Information?" (2004) 83 *Canadian Bar Review* 357-409.
27. Trudo Lemmens, "Confronting the Conflict of Interest Crisis in Medical

- Research” (2004) 23(4) *Monash Bioethics Review* 19-40.
28. Trudo Lemmens, “Piercing the Veil of Corporate Secrecy About Clinical Trials” (2004) 34(5) *Hastings Center Report* 14-18.
  29. Duff R. Waring and Trudo Lemmens. “Integrating Values in Risk Analysis of Biomedical Research: The Case for Regulatory and Law Reform” (2004) 54(3) *University of Toronto Law Journal* 249-290.
  30. Timothy Caulfield, Trudo Lemmens, Douglas Kinsella and Michael McDonald, “Research Ethics Review and the Role of Professional Bodies: A View from Canada” (2004) 32(2) *Journal of Law, Medicine & Ethics* 365-368.
  31. Trudo Lemmens, Dominique Sprumont, Herman Nys, Jerome Singh and Kathleen Cranley Glass. “CIOMS’ Placebo Rule and the Promotion of Negligent Medical Practice” (2004) 11 *European Journal of Health Law* 153-174.
  32. Bartha M. Knoppers, Trudo Lemmens, Béatrice Godard, Yann Joly, Denise Avar, Teren Clark, Pavel Hamet, Michael Hoy, Sébastien Lanctôt, Sandy Lowden, Huguette Martin, Christine Maugard, Yves Millette, Jacques Simard, Marie-Hélène Vachon and Frank Zinatelli, “Genetics and Life Insurance in Canada: Points to Consider” Supplement to "Physicians, genetics and life insurance" (27 April 2004) 170(9) *Canadian Medical Association Journal* 3pp. (online: <http://www.cmaj.ca/cgi/data/170/9/1421/DC2/1>)
  33. Trudo Lemmens, “Genetics and Insurance Discrimination: Comparative Legislative, Regulatory and Policy Developments and Canadian Options,” Special Edition: Precedent and Innovation: Health Law in the 21st Century, (2003) *Health Law Journal Special Supplement* 41-86.
  34. Trudo Lemmens and Paul B. Miller, “The Human Subjects Trade: Ethical and Legal Issues Surrounding Recruitment Incentives” (2003) 31 *Journal of Law, Medicine & Ethics* 398-418.
  35. Trudo Lemmens and Paul B. Miller, “Avoiding a Jekyll and Hyde Approach to the Ethics of Clinical Research and Practice” (2002) 2(2) *American Journal of Bioethics* 14-17.
  36. Trudo Lemmens and Bernard Dickens, “Canadian Law on Euthanasia: Contrasts and Comparisons” (2001) 8 *European Journal of Health Law* 135-155.
  37. Trudo Lemmens and Lisa Austin, “The Challenges of Regulating the Use of Genetic Information” (2001) 2(3) *ISUMA, Canadian Journal of Policy Research* 26-37.  
Simultaneous publication in French: “Les défis posés par la réglementation de l’utilisation de l’information génétique” *ISUMA* 28-39. Also forthcoming in UNESCO’s *EOLSS Encyclopedia of Life Support Systems*.
  38. Trudo Lemmens and Carl Elliott, “Justice for the Professional Guinea Pig” (2001) 1(2) *American Journal of Bioethics* 51-53.  
Also excerpted in Ezekiel J. Emanuel, Robert A. Crouch, John D. Arras,

- Jonathan D. Moreno and Christine Grady, eds., *Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary* (Baltimore, MD: Johns Hopkins University Press, forthcoming 2003), 183-85.
39. Trudo Lemmens and Alison Thompson, "Noninstitutional Commercial Review Boards in North America: A Critical Appraisal and Comparison with IRBs" (2001) 23(2) *IRB: Ethics and Human Research* 1-12.
  40. Trudo Lemmens and Benjamin Freedman, "Ethics Review for Sale? Conflict of Interest and Commercial Research Ethics Review Boards" (2000) 78(4) *Milbank Quarterly* 547-584.  
(Republished as book chapter (see above). Also excerpted in Ezekiel J. Emanuel, Robert A. Crouch, John D. Arras, Jonathan D. Moreno, and Christine Grady, eds., *Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary* (Baltimore, MD: Johns Hopkins University Press, 2003), 429-35.
  41. Marie Hirtle, Trudo Lemmens and Dominique Sprumont, "A Comparative Analysis of Research Ethics Review Mechanisms and the ICH Good Clinical Practice Guideline" (2000) 7 *European Journal of Health Law* 265-292.
  42. Trudo Lemmens, "Selective Justice, Genetic Discrimination and Insurance: Should We Single Out Genes in Our Laws?" (2000) 45 *McGill Law Journal* 347-412.
  43. Trudo Lemmens, "In the Name of National Security: Lessons from the Final Report of the Advisory Committee on Human Radiation Experiments." (1999) 6 *European Journal of Health Law* 7-23.
  44. Trudo Lemmens and Carl Elliott, "Guinea Pigs on the Payroll: The Ethics of Paying Healthy Subjects" (1999) 7(1) *Accountability in Research* 3-21.
  45. Kathleen Cranley Glass, Charles Weijer, Denis Cournoyer, Trudo Lemmens, Roberta M. Palmour, Stanley H. Shapiro and Benjamin Freedman, "Structuring the Review of Human Genetics Protocols, Part III: Gene Therapy Studies" (1999) 21(2) *IRB, A Review of Human Subjects Research* 1-9.  
Excerpted in Ezekiel J. Emanuel, Robert A. Crouch, John D. Arras, Jonathan D. Moreno and Christine Grady, eds., *Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary* (Baltimore, MD: Johns Hopkins University Press, 2003) 297-302.
  46. Trudo Lemmens and Peter A. Singer, "Bioethics for Clinicians: 17. Conflict of Interest in Research, Education and Patient Care" (1998) 159(8) *Canadian Medical Association Journal* 960-965.  
Response to letter to the editor by Stephen L. Sacks: Trudo Lemmens, "The Myth of Freedom from Conflict of Interest/One of the Authors Responds" (1999) 160(6) *Canadian Medical Association Journal* 784 (online: <http://www.cmaj.ca/content/160/6/784.2.full.pdf>).

47. Kathleen Cranley Glass, Charles Weijer, Trudo Lemmens, Roberta M. Palmour and Stanley H. Shapiro, "Structuring the Review of Human Genetics Protocols, Part II: Diagnostic and Screening Studies" (1997) 19(3/4) *IRB, A Review of Human Subjects Research* 1-13. Excerpted in Ezekiel J. Emanuel, Robert A. Crouch, John D. Arras, Jonathan D. Moreno and Christine Grady, eds., *Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary* (Baltimore, MD: Johns Hopkins University Press, 2003), 291-97.
48. Trudo Lemmens, "'What about your genes?' Ethical, Legal and Policy Dimensions of Genetics in the Workplace" (1997) 16(1) *Politics and the Life Sciences* 57-75.
49. Kathleen Cranley Glass, Charles Weijer, Roberta M. Palmour, Stanley H. Shapiro, Trudo M. Lemmens, and Karen Lebacqz, "Structuring the Review of Human Genetics Protocols: Gene Localization and Identification Studies." (1996) 18(4) *IRB, A Review of Human Subjects Research* 1-9. Excerpted in Ezekiel J. Emanuel, Robert A. Crouch, John D. Arras, Jonathan D. Moreno and Christine Grady, eds., *Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary* (Baltimore, MD: Johns Hopkins University Press, 2003) 185-291.
50. Trudo Lemmens, "Towards the right to be killed? Treatment refusal, assisted suicide and euthanasia in the United States and Canada," in G. Dunstan, et. al., eds., *Euthanasia, Death, Dying and the Medical Duty; British Medical Bulletin* (1996) 52(2) 341-353.
51. Trudo Lemmens, "Euthanasie en 'het goede leven.'" (with a commentary by P. Schotsmans), (1996) 6 *Ethische Perspektieven* 72-83. (author's translation into Dutch, with revisions, of "Euthanasia and the Good Life" – see following article)
52. Trudo Lemmens, "Euthanasia and the Good Life." *Perspectives in Biology and Medicine* (1995) 39(1): 15-27.
53. Trudo Lemmens, "Sports, Doping and Clashing Values," *Pandektis: the International Sports Law Review* (1994-1995) 2(1): 3-16 (Republished in 2000 as book chapter, cited above).

## **B. Books and Chapters**

### **Books (authored)**

1. Trudo Lemmens, Mireille Lacroix and Roxanne Mykitiuk (with a contributing chapter by Lisa Austin and Bitu Amani). *Reading the future? Legal and Ethical Challenges of Predictive Genetic Testing*. (Cowansville: Les Éditions Thémis, 2007), 308 pp.

### **Chapter in Books and Encyclopedia**

1. Trudo Lemmens and Carlos Herrera Vacaflor, "The Right to Health" in Henk Ten Have, ed., *Encyclopedia of Global Bioethics* (Springer, forthcoming 2015).
2. Shannon Gibson & Trudo Lemmens, "Overcoming 'Pre-Market Syndrome': Promoting Better Post-Market Surveillance in an Evolving Drug Development Context" in I. Glenn Cohen & Holly Lynch, eds., *FDA in the 21st Century: The Challenges of Regulating Drugs and New Technologies* (New York: Columbia University Press, forthcoming 2015)
3. Trudo Lemmens, "Informed Consent" in Yann Joly & Bartha M. Knoppers, *Routledge Handbook of Medical Law and Ethics*, (London: Routledge, 2015) 27-51.
4. Trudo Lemmens & Candice Telfer, "Clinical Trials Registration and Results Reporting and the Right to Health" in I. Glenn Cohen, *The Globalization of Health Care: Legal and Ethical Issues* (Cambridge (Mass): Oxford University Press, 2013) 255-271.
5. Trudo Lemmens & Candice Telfer, "L'accès à l'information et le droit à la santé : la transparence des essais cliniques comme une obligation dans le contexte des droits de l'homme" in Louise Lalonde, ed., *Le droit, vecteur de la gouvernance en santé? Défis théoriques et enjeux pratiques de l'accès aux soins de la santé* (Sherbrooke: Éditions Revue de Droit de l'Université de Sherbrooke, 2012) 131-167.
6. Trudo Lemmens, "Talk to Her, or Breaking the Silence of Neglected Bonds" in Sean Caulfield, Curtis Gillespie & Timothy Caulfield, eds, *Perceptions of Promise: Biotechnology, Society and Art* (Seattle: University of Washington Press, 2011) 9-13.
7. Trudo Lemmens, "Can Insurers Be Constrained to Accommodate the Genetically Disabled?" in C. Van Schoubroeck, W. Devroe, K. Geens & J. Stuyck, eds, *Over Grenzen: Liber Amicorum Herman Cousy* (Antwerpen/Cambridge: Intersentia, 2011) 185-196.
8. Yvonne Bombard & Trudo Lemmens, "Insurance and Genetic Information" (April 2010) in *Encyclopedia of Life Sciences* (Chisester (UK): John Wiley & Sons Ltd.) (DOI: 10.1002/9780470015902.a0005203.pub2) 1-6.
9. Trudo Lemmens & Lisa Austin, "The End of Individual Control Over Health Information: Governing Biobanks and Promoting Fair Information Practices" in Jane Kaye & Mark Stranger, eds, *Governing Biobanks* (Farnham (UK): Ashgate, 2009) 243-266.
10. Lisa Austin & Trudo Lemmens, "Privacy, Consent, and Governance" in Kris Dierickx & Pascal Borry, eds, *New Challenges for Biobanks: Ethics, Law and Governance* (Antwerpen: Intersentia, 2009) 111-122.

11. Dominique Sprumont & Trudo Lemmens, “Les conflits d’intérêts dans la recherche biomédicale” in Olivier Guillod, ed., *Conflits d’intérêts dans le système de la santé, 15<sup>e</sup> journée de droit de la santé* (Neuchâtel : Institut de droit de la santé de l’Université de Neuchâtel, 2009) 223-248.
12. Trudo Lemmens, “Biobanken en nieuw genetisch onderzoek: een uitdaging voor de bescherming van de privacy van medische gegevens” in Jan Wouters and Cedric Ryngaert, eds., *Mensenrechten: Actuele Brandpunten* (Leuven: Acco, 2008) 135-156.
13. Trudo Lemmens, “The Plasticized Pregnant Woman and Legal Rights over Reproductive ‘Material’” in Timothy Caulfield & Sean Caulfield, *Imagining Science* (Edmonton: University of Alberta Press, 2008) 60-62.
14. Trudo Lemmens, Lori Luther & Michael Hoy, “Genetic Information Access, a Legal Perspective: A Duty to Know or a Right Not to Know, and a Duty or Option to Warn?” (July 2008) *Encyclopedia of Life Sciences* (Chisester (UK): John Willey & Sons, 2008) (DOI: 10.1002/9780470015902.a0005188) 1-5.
15. Trudo Lemmens, “Institutional Conflicts of Interest” peer-reviewed chapter for on-line teaching manual, Charles Weijer & David McKnight, eds, *Bioethics Education Program, Royal College of Physicians and Surgeons*. (2008) 3.4.1. (online: <http://www.royalcollege.ca/portal/page/portal/rc/resources/bioethics/cases/section3>)
16. Trudo Lemmens, “Personal Conflict of Interest Medical Research: What Is It? What To Do About It?” peer-reviewed chapter for on-line teaching manual, Charles Weijer & David McKnight, eds, *Bioethics Education Program, Royal College of Physicians and Surgeons* (2008) 3.4.3. <http://www.royalcollege.ca/portal/page/portal/rc/resources/bioethics/cases/section3> (republished in slightly revised version in “Deontologie/Tuchtrecht”—see ‘other publications’)
17. Raymond Devries, Trudo Lemmens and Charles Bosk, “The subjectivity of objectivity: the social, cultural and political shaping of evidence-based medicine” in Belinda Bennett, Terry Carney and Isabel Karpin (eds) *The Brave New World of Health*, (Federation Press: Sydney, 2008) 144-165.
18. Lori Luther and Trudo Lemmens, “Human Genetic Data Banks: From Consent to Commercialization – An Overview of Current Concerns and Conundrums”, in Horst W. Doelle & Edgar J. DaSilva, eds., *Biotechnology*, [Eds.], in *Encyclopedia of Life Support Systems (EOLSS)* Developed under the Auspices of the UNESCO, (Oxford (UK): EOLSS Publishers, 2008) [<http://www.eolss.net>].
19. Trudo Lemmens and Lori Luther, “Financial Conflict of Interest in Medical Research” in Peter S. Singer and Adrian Viens, eds., *Cambridge*



*Textbook of Bioethics* (Cambridge: Cambridge University Press, 2008) 222-230. (online: [http://www.law.utoronto.ca/documents/Lemmens/cambridge\\_conflict\\_of\\_interest.pdf](http://www.law.utoronto.ca/documents/Lemmens/cambridge_conflict_of_interest.pdf))

20. Trudo Lemmens and Lisa Austin, "The Challenges of Genetic Information" in Horst W. Doelle & Edgar J. DaSilva, eds., *Biotechnology*, [Eds.], in *Encyclopedia of Life Support Systems (EOLSS)*, Developed under the Auspices of the UNESCO, (Oxford (UK): EOLSS Publishers 2008) [<http://www.eolss.net>] (revised republication of report for CBAC, see further).
21. Trudo Lemmens, "Conflict of Interest in Medical Research: Historical Developments" in Ezekiel E. Emanuel *et al.*, eds., *The Oxford Textbook of Clinical Research Ethics* (Cambridge: Oxford University Press 2008) 747-758.
22. Trudo Lemmens and Ron Bouchard, "Mandatory Clinical Trial Registration: Rebuilding Trust in Medical Research" in Global Forum for Health Research, *Global Forum Update on Research for Health, Volume 4: Equitable Access: Research Challenges for Health In Developing Countries* (London: Pro-Book Publishing, 2007) 40-46. (Translated in Portugese and published by Brazilian Federal Medical Council in: (2007) 15(1) *Revista Bioética* 49-64).
23. Trudo Lemmens, "Canadese regelgeving inzake medische keuringen voor verzekeringen" [Canadian regulations related to medical testing for insurance purposes] in H.Nys, H.Cousy, T.Lemmens & C. Van Schoubroeck (eds.), *Contactforum "Medische keuring bij private verzekeringen juridisch doorgelicht" 22 Maart 2007* (Brussel: Royal Flemish Academy of Belgium for Science and the Arts, 2008) 53-65.
24. Dominique Sprumont, Sara Girardin and Trudo Lemmens, "The Helsinki Declaration and the Law: an International and Comparative Analysis" in Andreas Frewer and Ulf Schmidt, eds., *History and Theory of Human Experimentation. The Declaration of Helsinki and Modern Medical Ethics* (Franz Steiner Verlag, 2007) 223-252.
25. Trudo Lemmens and Ron Bouchard, "Regulation of Pharmaceuticals in Canada" in J. Downie, T. Caulfield and C. Flood, eds., *Canadian Health Law and Policy*, 3<sup>rd</sup> ed. (Toronto: LexisNexis, 2007), 311-365.
26. Trudo Lemmens and Yves Thiery, "Insurance and Human Rights: What Can Europe Learn From Canadian Discrimination Law?" in Herman Cousy, Caroline Van Schoubroeck, eds. *Discriminatie in Verzekering/Discrimination et Assurance* (MAKLU-Academia Bruylant: Antwerpen, 2007) 253-294.
27. Trudo Lemmens and Remigius N. Nwabueze, "Showing Respect for the Dead: Fair Compensation for Research Autopsies in Malawi" in James V.

- Lavery, Elizabeth Wahl, Christine Grady and Ezekiel J. Emanuel, eds., *Case Studies in International Research Ethics* (New York: Oxford University Press, 2007) 287-294.
28. Trudo Lemmens, "Commercialized Medical Research and the Need for Regulatory Reform" in C. Flood, ed., *Just Medicare: What's In, What's Out, How We Decide* (Toronto: University of Toronto Press, 2006) 396-426. Also published in (2007) 5(3) *Icfai Journal of Health Care Law* 21-43 and as chapter in: A. Sabitha, ed., *Clinical Trials: Law and Regulations* (Amicus book & ICFAI University Press: Panjagutta, 2008) 74-105. 2
  29. Duff R. Waring and Trudo Lemmens, "Intégration des valeurs dans l'évaluation du risqué lié à la recherche biomédicale: arguments en faveur d'une réforme de la réglementation et du droit", in Commission du droit du Canada, *Le Droit et Le Risque: Mémoires du concours perspectives juridiques 2003* (Saint-Nicolas (Québec): Les Presses de l'Université Laval, 2006) 233-303. (Translation of "Integrating Values in Risk Analysis of Biomedical Research: The Case for Regulatory and Law Reform", see hereafter) 1
  30. Duff R. Waring and Trudo Lemmens, "Integrating Values in Risk Analysis of Biomedical Research: The Case for Regulatory and Law Reform," in: Law Commission of Canada, ed., *Law and Risk*, (Vancouver: University of British Columbia Press, 2005) 156-199 (first published in *Univ. Toronto LJ*, see above).
  31. Trudo Lemmens and Tom Archibald, "The CMA's *Chaoulli* Motion and the Myth of Promoting Fair Access to Health Care," in C. Flood, K. Roach and L. Sossin, eds., *Access to Care, Access to Justice* (University of Toronto Press, 2005) 323-346.
  32. Trudo Lemmens, "Les conflits d'intérêts dans le temple de la science médicale: diagnostic et options thérapeutiques" in Ysolde Gendreau, ed., *Dessiner la société par le droit/Mapping Society Through Law* (Montréal, Les Éditions Thémis, 2004) 77-115. (expanded version of chapter in Sprumont & Trutmann, *infra* and based on article *Leopards in the Temple*, see above).
  33. Trudo Lemmens, "Insurance and Human Genetics: Approaches to Regulation" in David N. Cooper, ed., *Nature Encyclopedia of the Human Genome*, (Houndmills, Basingstoke, Hampshire, Eng.: Macmillan, 2003) 495-498.
  34. Trudo Lemmens, "Contrôler les conflits d'intérêts dans le temple de la science" in D. Sprumont and M. Trutmann, eds., *La recherche avec les cellules souches : un défi ! Mais pour qui ? Rapport IDS Nr.3* (Genève : Georg, 2003) 7-21 (based on article *Leopards in the Temple*, see above).
  35. Trudo Lemmens, "Voorafgaande Wilsverklaringen in Canada: Evenwichtsoefeningen Tussen Autonomie, Bescherming van de Patiënt en

- Andere Maatschappelijke Belangen” [Advance Directives in Canada: Balancing Autonomy, Protection of Patients, and Other Social Interests] in Belgisch Raadgevend Comité voor Bio-Ethiek, A. van Orshoven and Y. Englert, eds., *“Levenstestament” en Andere Voorafgaande wilsverklaringen: [The “Living Will” and Other Advance Directives]* (Antwerp: Garant, 2003) 121-134. Translated into French: “Déclarations préalable de volonté au Canada: exercice de haute voltige entre autonomie, protection du patient et autres intérêts de la société” in Comité Consultatif de Bioéthique, ed., *“Testaments de vie” et autres directives anticipées* (Louvain-la-Neuve: Deboeck & Larcier, 2003) 108-121. (French translation of foregoing chapter.)
36. Trudo Lemmens and Benjamin Freedman, “Ethics Review for Sale? Conflict of Interest and Commercial Research Review Boards” in George F. Tomossy and David N. Weisstub, eds., *Human Experimentation and Research*, (Aldershot, Eng.: Ashgate, 2003) [republication of article, see above].
  37. Kathleen Cranley Glass and Trudo Lemmens, “Research Involving Humans” in J. Downie, T. Caulfield and C. Flood, eds., *Canadian Health Law and Policy*, 2<sup>nd</sup> ed. (Toronto: Butterworths, 2002) 459-500.
  38. Trudo Lemmens, “Sports, Doping and Clashing Values,” in D. Panagiotopoulos, ed., *Ethics in Sport* [Proceedings of the 2nd International Congress on Sports Law held in Olympia, Greece, 29-31 October 1993]. (Athens: Hellin, 2000) [republication].
  39. Kathleen Cranley Glass and Trudo Lemmens, “Conflict of Interest and Commercialization of Biomedical Research: What is the Role of Research Ethics Review?” in T. Caulfield and B. Williams-Jones, eds., *The Commercialization of Genetic Research: Ethical, Legal and Policy Issues* (New York: Plenum Press, 1999) 79-99.
  40. Trudo Lemmens, “Private Parties, Public Duties? The Shifting Role of Insurance in the Genetics Era,” in A. Thompson and R. Chadwick, eds., *Genetic Information: Acquisition, Access, and Control* (New York: Plenum Press, 1999) 31-39.
  41. Trudo Lemmens and Poupak Bahamin, “Genetics in Life, Disability and Additional Health Insurance in Canada: A Comparative Legal and Ethical Analysis” in B. Knoppers, ed., *Socio-Ethical Issues in Human Genetics* (Cowansville, PQ: Yvon Blais, 1998) 108-275.
  42. Trudo Lemmens, “Harm Reduction and Doping: The Clashing Values of Athletic Sports,” in P. Erickson, et al., eds., *New Public Health Policies and Programs for the Reduction of Drug Related Harms* (Toronto: Toronto University Press, 1997) 131-150.
  43. Hans van Houtte and Trudo Lemmens, “Internationale Koop” (co-authorship acknowledged in introduction) in G. Schrans and H. van

Houtte, *Internationaal Handels- en Financieel Recht* [International Trade and Financing Law], (Leuven: Acco, 1991) 256-327.

### C. Edited Books and Special Journal Issues

1. Trudo Lemmens and Duff R. Waring, eds., *Law and Ethics in Biomedical Research: Regulation, Conflict of Interest, and Liability*, (Toronto: University of Toronto Press, 2006) 257 pp.
2. Colleen Flood and Trudo Lemmens, editors of Special Peer-reviewed issue of the *Journal of Law, Medicine and Ethics*, on “Global Health and the Law” (2013) 41(1): pp. 9-300.
3. Herman Nys, Herman Cousy, Trudo Lemmens & Caroline Van Schoubroeck, eds, *Contactforum "Medische keuring bij private verzekeringen juridisch doorgelicht" 22 Maart 2007* [Medical Testing for Private Insurance: a Legal Diagnosis] (Brussel: Koninklijke Vlaamse Academie van België voor Wetenschappen en Kunsten [Royal Flemish Academy of Belgium for Science and the Arts], 2008), 65 pp. (Conference Proceedings).

## 2. Non-Refereed Publications

### A. Reports and Submissions to Governmental Committees and Scientific Organizations

1. The Expert Panel on Timely Access to Health and Social Data for Health Research and Health Systems Innovation, *Accessing Health and Health-Related Data in Canada*, (Ottawa: Council of Canadian Academies, 2015) 219 p. (online at: <http://www.scienceadvice.ca/uploads/ENG/Assessments%20and%20Publications%20and%20News%20Releases/Health-data/HealthDataFullReportEn.pdf>) I participated in the deliberations and discussions, commented and edited sections of the report, and provided background research, particularly in relation to chapters 4 and 5).
2. Trudo Lemmens, Thomas A. Ban, Louis C. Charland, *Final Report of the Independent Inquiry into the University of Ottawa, the Institute of Mental Health Research and the Ottawa Hospital*. Inquiry Conducted for the Canadian Association of University Teachers (March 2013), 81 pp. (online: <http://www.caut.ca/docs/default-source/reports/report-of-the-independent-committee-of-inquiry-into-the-university-of-ottawa-cimhr-and-roh.pdf?sfvrsn=0>)
3. Dario Kuzmanovic, Nivedita Ravi and Trudo Lemmens, *Management of Conflict of Interest in the Context of Research Ethics Review*, Report submitted to the World Health Organization (2013), 28 pp.
4. Shannon Gibson & Trudo Lemmens, “Regulating Off-Label Prescribing: the Good, the Bad, and the Uncertain” (April 2013) Memorandum

submitted to the Canadian Senate Standing Committee on Social Affairs, Science and Technology (April 2013) 10 pp.

5. Clinical Trials Advisory Group on Patient Confidentiality, “Final advice to the European Medicines Agency from the clinical trial advisory group on Protecting Patient Confidentiality” 30 April 2013 (online at: [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Other/2013/04/WC500142853.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/04/WC500142853.pdf)) (member advisory group)
6. Clinical Trials Advisory Group on Legal Aspects, “Final advice to the European Medicines Agency from the clinical trial advisory group on Legal Aspects” 30 April 2013 (online at [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Other/2013/04/WC500142857.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/04/WC500142857.pdf)) (member advisory group).
7. Trudo Lemmens, “Promoting Transparency of Clinical Trials: How is Canada Doing?” Memorandum submitted to the Canadian Senate Standing Committee on Social Affairs, Science and Technology (May 2012) 9 pp.
8. Trudo Lemmens & Shannon Gibson, “The Case for Improved Post-Market Surveillance of Pharmaceuticals” Memorandum submitted to the Canadian Senate Standing Committee on Social Affairs, Science and Technology (December 2012) 8 pp.
9. Cancer Care Ontario, *Mapping a Way Through the Double Helix: Making Sense of Personalized Medicine for Ontario’s Cancer System*, Report of a Signature Event, December 8, 2010. Summary of Proceedings (Toronto: Cancer Care Ontario, 2010) 41 pp. (contribution by sharing of lecture notes, slides and editing of section report)
10. Ubaka Ogbogu, Trudo Lemmens & Ruth Vale, *Privacy and Access to Genetic Research Data in the Context of Biobanks: Workshop Report* (Toronto, 2009) available at: <http://www.law.utoronto.ca/healthlaw/>.
11. Janice Graham (Chair), Ken Bassett, Ken Buchanan, Daniel Keene, Olaf Koester, Patrice Larose, Trudo Lemmens, Darcy Nicksy, Durhane Wong-Rieger, Expert Advisory Panel on the Special Access Programme: Record of Proceedings June 5-6, 2008 (Ottawa, 2008) 15 pp.
12. Tom Archibald and Trudo Lemmens, “After Capacity: The Legal and Ethical Problems of Data Collection from Legally Incompetent Subjects in Canada,” report submitted to the Canadian Institutes of Health Research, February 19, 2007, 58 pp.
13. Trudo Lemmens and Ron Bouchard, “Comments on the Legal, Regulatory and Ethical Aspects of the WHO Clinical Trial Registry Platform” Official Submission, WHO Clinical Trials Registration Platform (April 2006).

14. Trudo Lemmens and Tom Archibald, eds., *Genetic Information and the Law: Issues in the Insurance and Employment Settings*, by Lori Luther, Sasha Kontic and John Chenery. Report based on proceedings of Health Law Day conference held at the Faculty of Law, May 20, 2005 (Toronto: Bob Brown, 2006) 37 pp.
15. Trudo Lemmens and Tom Archibald, eds., *The Regulation and Organization of Research Ethics Review: Report of A Comparative International Workshop held at the Faculty of Law, University of Toronto, June 16-18, 2005*, prepared by Angela Long, Sasha Kontic, Elizabeth Cuellar Barroso and Daniel Brinza, (Toronto: Bob Brown, 2006), 102 pp.
16. Trudo Lemmens (as Chair, with Committee Members: Loren Falkenberg, Edith De Leury and Chantal Beauvais). *Report of the Ethics Review Committee* regarding implementation of the 1998 Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans, Submitted to the Canadian Institutes of Health Research, The National Science and Engineering Council and the Social Sciences and Humanities Research Council, December 20, 2002, 72 pp.
17. Trudo Lemmens and Roxanne Mykitiuk (as Co-Chairs, with Committee Members: M. Lacroix, L. Austin and B. Amani) *Legal and Ethical Challenges of New Predictive Genetic Testing*. Report of the Legal and Ethical Subcommittee of the Ontario Expert Advisory Committee on New Predictive Genetic Technologies, 164 pp.
18. Provincial Advisory Committee on New Predictive Genetic Technologies (including Trudo Lemmens, as Co-Chair of Legal and Ethical Issues Subcommittee), *Genetic Services in Canada: Mapping the Future*. Report of the Provincial Advisory Committee on New Predictive Genetic Technologies (Queen's Printer for Ontario, 2001) 116 pp. (online: [http://www.gov.on.ca/health/english/pub/ministry/genetic\\_rep02/genetic\\_rep.html](http://www.gov.on.ca/health/english/pub/ministry/genetic_rep02/genetic_rep.html))
19. Trudo Lemmens and Lisa Austin, "Volume, Depth and Speed: The Challenges of Genetic Information" discussion paper prepared for the Canadian Biotechnology Advisory Committee (2001) (online at [http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/vwapj/GenInfo\\_Challenges\\_Lemmens\\_e.pdf/\\$FILE/GenInfo\\_Challenges\\_Lemmens\\_e.pdf](http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/vwapj/GenInfo_Challenges_Lemmens_e.pdf/$FILE/GenInfo_Challenges_Lemmens_e.pdf)), 40 pp. (Shorter version published as an article in *ISUMA*)
20. Robert Crouch, Richard Elliott, Trudo Lemmens and Louis Charland, *Complementary/Alternative Health Care and HIV/AIDS: Legal, Ethical and Policy Issues in Regulation*, Report for the Canadian HIV/AIDS Legal Network (Montreal: Canadian HIV/AIDS Legal Network, 2001) 164 pp. Online at: <http://www.aidslaw.ca/Maincontent/issues/cts/cam/toc.htm>. (Also available in French)

21. Marie Hirtle, Trudo Lemmens and Dominique Sprumont, *A Comparative Analysis of Research Ethics Review Mechanisms and the ICH Good Clinical Practice Guideline*. Report Submitted to the Council of Europe (1999) 41 pp. (Shorter version published as an article).
22. Trudo Lemmens and Poupak Bahamin, *Genetics in Life, Disability and Additional Health Insurance in Canada: a Comparative Legal and Ethical Analysis*. Report prepared for the Medical, Ethical, Legal and Social Issues Committee of the Canadian Genome Analysis and Technology Program (Montréal: Université de Montréal, Centre de Recherche en Droit Public, 1996) 188 pp. (Revised version subsequently published as book chapter).
23. Sonia Lebris, B.M. Knoppers and Trudo Lemmens, *Évaluation éthico-juridique du projet de carte de santé de Rimouski*. Report prepared for the “Commission d'accès à l'Information du Québec” (1995) 60 pp.
24. Trudo Lemmens, *Belgisch Vreemdelingenrecht 1990 [Belgian Law in relation to foreigners, 1990]*, Report for the European Commission, Leuven (1991) 60 pp.

## **B. Book Reviews**

1. Trudo Lemmens, “Is there a lack of ethical integrity in drug clinical trials?” [Review of the book *Medical Research for the Hire: The Political Economy of Pharmaceutical Clinical Trials* by Jill A. Fisher] (2010) 29(10) *Health Affairs* 1966-1967.
2. Trudo Lemmens, “Medical Law in New Zealand” [Review of the book *Medical Law in New Zealand* by PDG Skegg, Ron Paterson, Joanna Manning, John Dawson, Nicola Peart and Warren Brookbanks] (2008) 11(4) *Otago Law Review* 717-723.

## **C. Other Non-Refereed Publications: Papers, Opinion Pieces, Letters, Blog posts.**

1. Shannon Gibson & Trudo Lemmens, “The Promise and Peril of Adapting the Regulatory System to the Pharmacogenomic Context: New Paper McGill Journal of Law & Health” *University of Toronto Faculty of Law Blog*, June 11, 2015. Available at: <http://www.law.utoronto.ca/blog/faculty/promise-and-peril-adapting-regulatory-system-pharmacogenomic-context-new-paper-gibson>
2. “Minnesota Legislature Must Hold Hearings on Psychiatric Research Misconduct” *University of Toronto Faculty of Law Blog*, May 5, 2015. Available at: <https://www.law.utoronto.ca/blog/faculty/minnesota-legislature-must-hold-hearings-psychiatric-research-misconduct>

3. “The Pharmaceutical Industry’s Shift towards Niche Markets and ‘Personalized Medicine’: New Article Reports on Qualitative Study and Critically Analyzes Ethical and Regulatory Challenges,” *University of Toronto Faculty of Law Blog*, April 17, 2015; available at: <https://www.law.utoronto.ca/blog/faculty/pharmaceutical-industry-s-shift-towards-niche-markets-and-personalized-medicine-new>
4. “Decreasing the Data Deficit: Improving Canada's Drug Regulatory System,” *University of Toronto Faculty of Law Blog*, April 15, 2015. Available at: <https://www.law.utoronto.ca/blog/faculty/decreasing-data-deficit-improving-canadas-drug-regulatory-system>
5. “Paper Shannon Gibson & Trudo Lemmens on Pharmaceutical Innovation and Drug Regulatory Changes Available Online: Niche Markets and Evidence Assessment in Transition,” *University of Toronto Faculty of Law Blog*, December 16, 2014. Available at: <https://www.law.utoronto.ca/blog/faculty/new-paper-gibson-lemmens-pharmaceutical-innovation-and-drug-regulatory-changes-niche>
6. Trudo Lemmens, “EMA’s Proposed Data Release Policy: Promoting Transparency or Expanding Pharma Control over Data?” (guest blog) *PLoS Speaking of Medicine*, May 30, 2014, <http://blogs.plos.org/speakingofmedicine/2014/05/30/emas-new-data-release-policy-promoting-transparency-expanding-pharma-control-data/>
7. Tom Jefferson, Peter Doshi & Trudo Lemmens, “EMA’s Data Sharing Policy--Towards Peeping Tom Medicine?” *BMJ Blog* May 22, 2014, <http://blogs.bmj.com/bmj/2014/05/22/tom-jefferson-et-al-emas-data-sharing-policy-towards-peeping-tom-based-medicine/>
8. “Markinson Case Update: How an institution can transform a request for an ‘Independent Inquiry’ into another institutional procedural shield,” *University of Toronto Faculty of Law Blog*, April 24, 2014. Available at: <https://www.law.utoronto.ca/blog/faculty/markinson-case-update-how-institution-can-transform-request-independent-inquiry>
9. Trudo Lemmens, “Hyping Mass Vaccinations” Letter to the Editor, *Edmonton Journal*, January 6, 2014 (online: <http://www.edmontonjournal.com/health/More+letters+Massive+farms+major+environmental+damage/9356019/story.html>)
10. Trudo Lemmens, “Markinson Case: University of Minnesota sets up Inquiry, but will it be independent? And what will it do?” *University of Toronto Faculty of Law Blog*, December 19, 2013 (online: <https://www.law.utoronto.ca/blog/faculty/markinson-case-university-minnesota-sets-independent-inquiry-what-will-it-do>)
6. Trudo Lemmens, “University of Minnesota Should Investigate Suicide in Clinical Trial, Scholars Argue” Blog Post, *University of Toronto Faculty of Law Blog*, October 24, 2013. (online at:



<https://www.law.utoronto.ca/blog/faculty/university-minnesota-should-investigate-suicide-in-clinical-trial-scholars-argue>)

7. Trudo Lemmens & Shannon Gibson, “Comparative Table: Overview of ‘reviews’ of the Markingson Case, November 14, 2013, 7 pp. (online: [http://www.law.utoronto.ca/utfl\\_file/count/users/lemmenst/Markingson%20FINAL2%20Nov%2014.pdf](http://www.law.utoronto.ca/utfl_file/count/users/lemmenst/Markingson%20FINAL2%20Nov%2014.pdf)) (attachment to November 13 letter re Markingson case)
8. Trudo Lemmens, Raymond Devries, Alice Dreger, Lois Shepherd, Susan Reverby, Jerome Kassirer, Letter to President Kaler, Professor Von Dassow, and Senators of the University of Minnesota, October 21, 2013. (and follow-up letters re Markingson case, November 13 and December 11, 2013).
9. Trudo Lemmens “Individual Researcher Conflict of Interest in Biomedical Research: What Can Be Done About It?” (2013) 1 *Deontologie/Tuchtrecht* 51-61 (slightly revised version of online chapter for teaching manual College of Physicians and Surgeons of Canada (see above).
10. Letter re Health Canada Interview on Clinical Trials Data, *Macleans online*, Science-ish, November 5, 2012 (online at: <http://www2.macleans.ca/2012/11/05/why-is-canada-such-a-laggard-on-clinical-trials-regulation/>).
11. “Anglophone Media Using Protest to Attack All Things Quebec” blog, *Huffington Post Canada*, 31 May 2012 (online at: [http://www.huffingtonpost.ca/trudo-lemmens/quebec-protest-coverage\\_b\\_1559079.html](http://www.huffingtonpost.ca/trudo-lemmens/quebec-protest-coverage_b_1559079.html)).
12. Simon Stern & Trudo Lemmens, “Opinion: Ghost Writing is Fraudulent” *The Scientist*, December 2, 2011 (online at: <http://www.the-scientist.com/?articles.view/articleNo/31347/title/Opinion--Ghost-Writing-is-Fraudulent/>).
13. Trudo Lemmens & Simon Stern, Letter to the Editor, *Globe and Mail*, August 6, 2011.
14. “The Assisted Human Reproduction Act and the Supreme Court of Canada” *Guestblog for TVO The Agenda*, Nov. 4, 2011. (online: <http://theagenda.tv.org/blog/agenda-blogs/guest-blog-assisted-human-reproduction-act-and-supreme-court-canada>).
15. “Is Privacy Really at the Heart of the Mandatory Census Change” (Opinion) (August 23, 2010) *The Hill Times* 7. (also reproduced in University of Toronto, Faculty of Law Blog)
16. Trudo Lemmens, “Annex 1: Financial Conflict of Interest in Medical Research”, in World Health Organization, *Research Ethics Committees: Basic Concepts for Capacity Building* (booklet prepared by Carl Coleman,

- Trudo Lemmens, Tarun Mehra and Aissatou Touré & Marie-Charlotte Bouësseau (coordinator), (Geneva: World Health Organization, 2009) 71 pp. (also available in French) (Annex 1: 50-57).
17. Letter to the editor re “Clarifying Coercion” (January-February 2006) *Hastings Center Report* 6-7.
  18. Trudo Lemmens, “Pharmaceutical Industry Interests and the Integrity of Medical Research: Strengthening the Regulatory System” *Innovate Magazine* (Spring 2006) 28-31.
  19. Carl Elliott and Trudo Lemmens “Ethics For Sale: For-profit ethical review, coming to a clinical trial near you.” (2005), *Slate* (on-line periodical) December 13, 2005 (online: <http://www.slate.com/id/2132187/>).
  20. “Ensure Integrity in Industry Links” [Letter to the Editor] *Times Higher Education Supplement*, December 2, 2005. (Online: <http://www.timeshighereducation.co.uk/comment/letters/ensure-integrity-in-industry-links-3/200122.article>)
  21. Trudo Lemmens, Yann Joly and Bartha M. Knoppers, “Genetics and life insurance: A Comparative Analysis” (2004) 2(2) *GenEdit* (on-line publication, available at <http://www.humgen.umontreal.ca/en/GenEdit.cfm>) 15 pp. Also available in French: “Génétique et assurance vie: analyse comparative” (2004) 11(2) *GenEdit*, 1-14.
  22. Trudo Lemmens, “Why regulate new genetics” *Innovate Magazine* (Spring 2004), 14-17.
  23. Trudo Lemmens, “Why regulate the new genetics?” (2003) 83 *Reform: A Journal of National and International Law Reform* 41-46.
  24. Trudo Lemmens, “Préface” in G. Cardinal, *Les dimensions normatives de la thérapie génique* (Montréal: Les Éditions Thémis, 2003) XI-XIII.
  25. Trudo Lemmens and Jerome Singh, “Moral Duty But Also Self-Interest Requires A Greater Commitment To the South” (2003) 8(2) *Canadian Bioethics Society Newsletter* 5-7.
  26. Trudo Lemmens, “SARS is bad, malaria is worse,” *The National Post*, May 2, 2003, third in a series of articles by U of T law school faculty members written in conjunction with the conference “Anatomy of a Crisis: Law and Policy Responses to SARS.” Article online at: [http://www.law.utoronto.ca/faculty\\_content.asp?itemPath=1/7/0/0andcontentId=702](http://www.law.utoronto.ca/faculty_content.asp?itemPath=1/7/0/0andcontentId=702).
  27. Trudo Lemmens, “Regulating the Trade in Human Research Subjects,” *Nexus* (Fall/Winter 2002) 25-27.

28. Paul B. Miller and Trudo Lemmens, "Finder's Fees and Therapeutic Obligations" (2002) 5(1) *Geriatrics and Aging* 66-69.
29. Trudo Lemmens, "Reading the Book of Life: now that we have a partial script for human genes, who should read it--and how should it be sold?" *University of Toronto Bulletin* (February 26, 2001): 16.
30. Trudo Lemmens, "Impact of Legalization" in "Pro and Contra. A Time to Die: Is there a Place in Medicine for Euthanasia?" (2001) 9(3) *Parkhurst Exchange* 25.
31. Trudo Lemmens and Paul B. Miller, "Balancing Ethical Research Issues in Psychiatry" (2000) 17(6) *Psychiatric Times* 63-67.
32. Trudo Lemmens (contribution as Chair of the Panel, with presenters P.S. Appelbaum, W. Carpenter, C. McCarthy, C. Peterson, D. Streiner and C. Weijer), "Placebo-controlled studies in schizophrenia: ethical and scientific perspectives. Panel discussion" (1999) 35 *Schizophrenia Research* 227-236.
33. Trudo Lemmens, "Genetic Testing: A Profile" *Unum Advisor* (Winter 1998): 1-3.
34. Trudo Lemmens, "Benjamin Freedman: A Life of Commitment." (1997) 8(1) *National Council on Bioethics in Human Research Communiqué* 6-7.
35. Trudo Lemmens, "A Response to the Parliamentary Sub-Committee's Report and Recommendations on Compassionate Access to Experimental Drugs of the Parliamentary Subcommittee on HIV/AIDS." (1997) 3(2-3) *Canadian HIV/AIDS Policy & Law Newsletter* 40-43. Also in French: "Reaction au rapport et aux recommandations du sous-comite parlementaire" (1997) 3(2-3) *Canadian HIV/AIDS Policy & Law Newsletter* 46-49.
36. Trudo Lemmens, "Compassionate Access to Experimental Drugs" (1996) 3(1) *Canadian HIV/AIDS Policy & Law Newsletter* 41-44.
37. Trudo Lemmens, "US Appeal Courts Rule in Favour of Assisted Suicide" (case comment) (1996) 2(4) *Canadian HIV/AIDS Policy and Law Newsletter* 1, 42-43.
38. Trudo Lemmens, "Legalizing Euthanasia" (1995) 2(1) *Canadian HIV/AIDS Policy & Law Newsletter* 7-9.
39. Trudo Lemmens, "Oregon's Measure 16 Declared Unconstitutional" (1995) 2(1) *Canadian HIV/AIDS Policy and Law Newsletter* 10.

40. Trudo Lemmens, “Bank's Drug Testing Program: Not Discriminatory, but Intrusive” (case comment) (1995) 1(2) *Canadian HIV/AIDS Policy and Law Newsletter* 4-5.
41. Trudo Lemmens, “L'utilisation de l'information génétique par les compagnies d'assurances” *L'Actualité Médicale*, 29 September 1993: 42-43.

### **3. Manuscripts/publications, etc. in preparation and submitted to publishers but not yet accepted**

#### **A. Articles**

1. “Access to Clinical Trials Data and Commercial Secrecy: Critical Comments on the European Court’s Assessment of the European Medicine’s Agency Transparency Policy” (in preparation).
2. “Examining ‘academic entrepreneurship’ and the goals of health research policy”. (with R. Axler, FA Miller, M. Painter-Main) (RA lead author; manuscript in preparation for submission to *Academic Medicine*).
3. “The Impact of SARS on Research Ethics Review” (with Catherine M Tansey, Stephanie A. Nixon, Ronald Heslegrave, Margaret S. Herridge, James V. Lavery) (CMT lead author; submitted to *Journal of Empirical Research on Research Ethics*).
4. “Research Ethics and Pharmaceutical Policy Challenges of Targeted Drug Development and Marker Selection: A Case Study Analysis” (with Hamid Raziee and Jonathan Kimmelman) (first draft)
5. Dario Kuzmanovic, Nivedita Ravi and Trudo Lemmens, *Management of Conflict of Interest of Research Ethics Boards and Research Ethics Board Members*, article to be finalized, based on Report submitted to World Health Organization (see above).
6. “Blowing the Whistle on the Canadian Pharma Industry: The Need for Legislative Protection” (with Sean Adair) (first draft finalized).
7. “Holding the Pharmaceutical Industry Accountable Through the Criminal Law” (preliminary draft).

#### **B. Books**

Trudo Lemmens, Andrew Martin, Ian Lee & Cheryl Milne (eds), *Assisted Human Reproduction: Ethical Qualms, Legal Challenges* (provisional title) (book contract with University of Toronto Press). Book submitted for publication. Being resubmitted with revisions following positive peer-review.

## **C. Chapters**

“The Commodification of Human Reproduction: In Defense of Banning the Commercial Sale of Gametes” in Trudo Lemmens, Andrew Martin, Ian Lee & Cheryl Milne (eds), *Assisted Human Reproduction: Ethical Qualms, Legal Challenges* (provisional title) (book contract with University of Toronto Press)

## **In Progress**

1. “Does Canada Need Sunshine Legislation to Curb Pharmaceutical Industry Influence Peddling?”
2. “A Review and Critical Analysis of Biobank Access and Data Transparency Policies in Canada” (with S. Gibson & RA Axler).

## **4. Papers and Posters Presented at Meetings and Symposia (peer-reviewed abstracts)**

1. R. Axler, S. Gibson, T. Lemmens “Assessing the Scope and Constraints of Industry Access to Publicly-Funded Biobanks in Canada”. Abstract accepted for Poster presentation at the International Society for Biological and Environmental Repositories Annual Meeting, Phoenix AZ, May 5-9, 2015.
2. S. Gibson & T. Lemmens, “Tensions Point in Niche Markets and Personalized Medicine: A Qualitative Study of the Perspectives of Canadian Stakeholders.” Poster presentation SG at the UBC Centre for Health Services and Policy Research annual conference “Sticker Shock”. Vancouver, BC, March 3, 2015.
3. R. Axler, FA Miller, P. Lehoux & T. Lemmens, “Navigating Conflict of Interest in Entrepreneurial Laboratories: A Canadian Study”. Presented at the Annual Meeting of the Society for Social Studies of Science, San Diego, CA, October 9-12, 2013.
4. S. Gibson, T. Lemmens, H. Raziee, "Ethical, Legal and Social Issues in Pharmacogenomics: A Qualitative Study of the Perspectives of Canadian Stakeholders". Poster Presentation by SG at the Keystone Symposium "Human Genomics and Personalized Medicine". Stockholm, Sweden, June 17-21, 2013.
5. S. Gibson, T. Lemmens, H. Raziee. "Ethical, Legal and Social Issues in Drug Development and Pharmacogenomics: A Qualitative Study of the Perspectives of Canadian Stakeholders". Presented by SG at the Canadian Association for Health Services and Policy Research Annual Conference 2013 "Making Good on the Triple Aim: How to Improve our Success within the Canadian Context". Vancouver, BC, Canada, May 29, 2013.

6. S. Gibson, T. Lemmens, H. Raziee. "Ethical, Legal and Social Issues in Drug Development and Pharmacogenomics: A Qualitative Study of the Perspectives of Canadian Stakeholders". Presented by SG at the Canadian Agency for Drugs and Technologies in Health 2013 Symposium "Evidence in Context". St. John's, NL, Canada, May 7, 2013.
7. S. Gibson, T. Lemmens, "Ethical, Legal and Social Issues in Drug Development and Pharmacogenomics: Report on a Qualitative Study of the Perspectives of Canadian Stakeholders". Presentation by SG at the workshop Genetic Transparency: Ethical and social implications of next generation genetic technologies and genomic medicine. Luebeck, Germany, March 20, 2013.
8. S. Gibson, T. Lemmens, H. Raziee "Ethical, Legal and Social Issues in Drug Development and Pharmacogenomics: A Qualitative Study of the Perspectives of Canadian Stakeholders". ]]Presented by SG as a poster at the Pharmacare 2020 Conference. Vancouver, BC, Canada, Feb. 26-27, 2013.
9. Hamid Reza Raziee, Trudo Lemmens & Jonathan Kimmelman, "When Genetic Make-up Determines Inclusion in Clinical Trials, Is There a Need to Represent the Excluded?" American Society for Bioethics and the Humanities, Annual Meeting, October 20, 2012. (abstract accepted for presentation but presentation cancelled)
10. R. Axler, F.A. Miller, P. Lehoux & T. Lemmens, "Managing the boundaries of basic research commercialization and conflict of interest: The views and values of academic biomedical researchers" Presented by RA at the Canadian Bioethics Society Annual Meeting, Montreal, QC, May 31-June 2, 2012.
11. R. Axler, F.A. Miller, P. Lehoux & T. Lemmens, "Mapping the Complex Cartography of Health Research Commercialization: A Study of Canadian Basic Biomedical Researchers". Poster presentation RA at the Canadian Association of Health Services and Policy Research Annual Conference. Montreal, QC, May 29-31, 2012.
12. R. Axler, F.A. Miller, P. Lehoux & T. Lemmens, "Commercialization and Conflicts of Interest: A Study of Canadian Academic Biomedical Researchers". Presented by RA at the American Society of Bioethics and Humanities Annual Conference. Minneapolis, USA, October 13-16, 2011; and at the Canadian Bioethics Society Annual Meeting. Saint John, NB, Canada, June 3, 2011.
13. R. Axler, F.A. Miller, P. Lehoux, T. Lemmens & E. Mentzakis, "Academic Biomedical Researchers' Attitudes to Research Commercialization in Canada". Poster presented by RA at the Canadian Association for Health Services and Policy Research. Halifax, Canada, May 9-12, 2011.

14. "Governing Biobanks and Fair Information Practices" presentation at the Conference "New Challenges for Biobanks. Ethics, Law and Governance" K.U.Leuven, 18-20 May 2009.
15. "The Promotion of Fair Research Practices in Biobank Research: Are Research Ethics Committees Up to the Job?" presentation at the 9<sup>th</sup> World Congress of Bioethics, Rijeka (Croatia), September 8, 2008.
16. "Fair Information Practices and the Role of Research Ethics Committees" presented at "Governing Biobanks: What Are the Challenges?" 2008 International Congress, St. Anne's College, University of Oxford, June 25, 2008.
17. "Prohibiting the Sale of Human Reproductive Material?" presentation at "Health, Law and Policy in Canada and the United Kingdom: Common Challenges, Divergent Directions?" British Association for Canadian Studies, Legal Studies Group, International One Day Conference 2008, Canada House, London, Friday July 4, 2008.
18. "Coercion and undue influence: moral terminology in context" Congress on Law and Mental Health, International Association of Law and Mental Health, Padua, Italy, June 29, 2007.
19. "Prohibiting the Sale of Human Reproductive Material and Human Flourishing" New Pathways for European Bioethics, Leuven, European Association of Centres of Medical Ethics, Annual Conference, Katholieke Universiteit Leuven, 30 September 2006.
20. "Pricked by the Porcupine: Commercialization and Academic Integrity" presentation at the 17<sup>th</sup> Annual Conference of the Canadian Bioethics Society, "Bioethics Confronts Dollars and Sense," Halifax, October 21, 2005.
21. "The Commercialization of Medical Research: The Case for Regulatory Reform" presentation at the 29<sup>th</sup> International Congress on Law and Mental Health, International Academy of Law and Mental Health, Paris, July 8, 2005.
22. "Defining Genetic Information: Volume, Depth and Speed" Presentation, XXVI<sup>th</sup> International Congress on Law and Mental Health, Montreal, July 4, 2001.
23. "Conflict of Interests and Funding of Research." Presentation, Bioethics Summer Retreat, Jiminy Peak, Massachusetts, June 19, 2001.
24. "Weighing Risks and Benefits in Mental Health Research: In Search of a Fine Balance." Presentation, 25<sup>th</sup> Annual Congress of the International Academy of Law and Mental Health, Siena, July 13, 2000.
25. "Defining Genetic Information: Volume, Depth and Speed" Presentation,

- XXVIth International Congress on Law and Mental Health, Montreal, July 4, 2001.
26. "Conflict of Interests and Funding of Research." Presentation, Bioethics Summer Retreat, Jiminy Peak, Massachusetts, June 19, 2001
  27. "Weighing Risks and Benefits in Mental Health Research: In Search of a Fine Balance." Presentation, 25<sup>th</sup> Annual Congress of the International Academy of Law and Mental Health, Siena, July 13, 2000.
  28. "New Models for Institutional Review Boards." Presentation, the 11<sup>th</sup> Annual Bioethics Summer Retreat, Hot Springs, Virginia, June 19, 1999.
  29. "Competency to Refuse Medical Treatment and Fitness to Stand Trial: The Ethical Dilemma of Compulsory Treatment." Presentation, XXIVth International Congress on Law and Mental Health, June 17, 1999.
  30. "The Shifting Role of Insurance in the Genetics Era", Presentation, 10<sup>th</sup> Annual Bioethics Summer Retreat, Brewster MA, June 19, 1998.
  31. "Private Parties, Public Duties? The Shifting Role of Insurance Companies in the Genetics Era." Presentation at the International Conference on Genetic Information: Acquisition, Access and Control, Preston (U.K.), December 5, 1997.
  32. "Are Research Subjects Underpaid?" Presentation at the 9th annual Canadian Bioethics Society Conference, Halifax, October 17, 1997.
  33. "Conflict of Interest in Private IRBs." Presentation at the III World Congress of Bioethics, San Francisco, November 22, 1996.
  34. "Génétique et assurances: l'équité, l'égalité et les limites de la liberté contractuelle." Presentation at the Annual Conference of the "Association Canadienne Française pour l'Avancement de la Science," Colloquium on the Social and Ethical Issues of the Human Genome Project, Montreal, May 14, 1996.
  35. "When my Genome Disables Me, Am I then Protected by Law?" Presentation at the 7th Annual Congress of the Canadian Bioethics Society, Vancouver, November 25, 1995.
  36. "Euthanasia and the Good Life." Presentation Prize Winning Paper at the Annual Meeting of the Society for Health and Human Values, Pittsburgh, October 8, 1994.