

**York University Faculty of Health
Faculty of Graduate Studies, Graduate Program in Health
Fall 2017**

GS/HLTH 5440 3.0 Globalization, Pharmaceuticals and Health Equity

Course Director: Dr. Michelle Wyndham-West

Email: mwywest@yorku.ca

Course Time: Wednesdays, 2:30 pm to 5:30 pm

Course Location: R S104

Office Location and Hours: Room HNES 422

Wednesdays from 5:45 pm to 6:45 pm and Fridays from 2:45 pm to 4:45 pm or by appointment in person or via Skype

Course announcements and course material will be available through Moodle.

Course Description:

Globalization in the pharmaceutical area has sparked debate about a series of issues that impact on health equity. These issues centre around two central themes: access to pharmaceuticals and ethics. The first part of the course will explore political and sociological theories in order to develop a theoretical toolkit to critically examine current policy trends in global pharmaceutical policies. After this introduction, the course moves to an examination of human rights frameworks and international health agency involvement in access to pharmaceutical policy and programmes, including the proliferation of public private partnerships on the international stage and their programs to re-dress drug access in the Global South. We then turn to the internationalization of clinical trials and drug research practices in the Global South, as well as “big pharma” global expansion and marketing strategies and their implementation.

Mid-way through the course we will cover the history of intellectual property rights (IPRs) and how and why the industry and its political supporters have been successful in strengthening IPRs, which has exacerbated limited access to necessary drugs in the Global South. After this, we will cover in detail three case studies situated in Global Health contexts – 1) vaccination, 2) mental health and 3) pain management and palliative care - which tie together the issues of drug access and ethics from a macro policy perspective and through the lived experiences of individuals and communities on the ground who must negotiate these policies in quotidian situations. We will then wrap-up the course by reviewing proposed policy solutions in the form of the Health Impact Fund, patent pools and open source drug discovery, which are being mulled over to loosen the grip intellectual property rights have in determining limited access to pharmaceuticals in the global south.

Throughout the course we will be mindful to critically unpack the manifest and latent consequences of hegemonic human rights discourses propagated by

international health agencies surrounding drug access and equity, including the pharmaceuticalization and judicialization of global public health policy and programming.

Course Objectives:

1. Understand current issues in global pharmaceutical policy as they play out on macro and micro levels. This involves critically examining pharmaceutical policymaking processes and products and the direct effects of these policies on everyday lives of individuals and societies.
2. Evaluate how politics and ethics form, shape, limit and expand pharmaceutical policy, including the pharmaceuticalization and judicialization of global public health policy and programming.
3. Develop oral and written skills in analyzing and communicating complex pharmaceutical policy issues in a clear and compelling way.

Course Structure:

The issues that we will be discussing are often complex and require background knowledge. The background presentations will be provided by the course director and last about 20-30 minutes. They are designed to allow the rest of the class to understand some of the background behind the issues being discussed.

Following the background presentations, one (or more) student(s) will lead the discussion. The discussion is based on the readings and should bring out the main themes in the readings. After about each 15 minutes or so students should use the themes to formulate and present to the class one or more questions about the material that they have covered to stimulate and guide discussion. The presentations should be limited to a maximum of 45 minutes, leaving about 1 1/2 hours for discussion. The presentations should explain how the readings relate to the three themes of this course: pharmaceuticals, globalization and health equity. The mark will be based on how well the information in the readings is summarized, how well organized the presentation is, how good the analysis of the readings is and the overall understanding that students demonstrate of the topic through their presentation and leadership of the discussion.

The method of presentations (e.g., Powerpoint slides, overheads, use of blackboard) is not relevant to the grade. Speaking style is not relevant to the grade.

Each student will be expected lead (or co-lead) one discussion during the course.

Presentations and discussions lead by students are expected to take up about 2 hours in total. If presentations and discussions are shorter marks will be deducted.

In addition to leading discussions students are expected to participate in class with thoughtful questions and contributions. Students will be assessed on the quality of their contributions to class participation, their ability to critically read and understand course materials. Persistent absence from class prohibits your full participation and will result in a lower grade. **For each class where there is not adequate participation 1 (of 10) marks will be deducted.**

Weekly Summaries or Essay

Every student is expected to participate fully in each class, coming prepared by reading and engaging in both presentations and debates. For each class, students will prepare a critical assessment of one or more of the readings. These summaries should be in the form of an “editorial”, that is they should identify the main themes in one or more of the readings and then provide a critical commentary about these themes. As with the seminar discussions the summaries should focus on the three themes of the course: pharmaceuticals, globalization and health equity. These assessments should be 750 words (minimum 700, maximum 800). Students can submit as many summaries as they want. Only the top 8, in terms of marks, will count towards the final mark. Each assignment is worth 7.5% of the final mark.

Marks for the summaries will be based on writing style, how well the summaries display an understanding of the issue(s) and the originality of the thought behind the commentary about the issue(s).

Those who do not want to hand in weekly summaries can do an essay on one of the topics covered in this course. The essay should be 6000 words (range 5500 to 6500 words). A marking scheme for the essay will be distributed if there are any students who choose this option.

Course Evaluation:

Assignment	Percent of final grade
Seminar discussion	30%
Weekly summaries or essay	60% (7.5% for each summary x 8)
Participation	10%

Course Material:

Most reading materials are available on the York University library web site or are public policy documents, which are available on the Internet. Five readings (which are indicated with an asterisk) will be available through a course kit, which is expected to be for sale in late September or early October, which is in advance of when the readings are assigned. As such, the cost for course materials will be low.

Library Resources

If you are looking for resources for your summaries or your seminar discussions there are web pages that can be accessed through the York Library web site that may be of a lot of value. There is the Health Studies Guide and a new Disability Studies Guide that are both accessible from the [library's home page](#). Once there click on "[Find Articles by Subject](#)". Resources of note in the [Critical Disability Studies Guide](#) include the Rehabdata Database, which is a free online database and covers issues related to different types of disabilities and rehabilitation. Some articles in this database are available full-text and there's also an online chat available for assistance!

In case you are not aware of the Canadian Health Resource Collection (also listed in the Health and Disability Studies Guide), it is another useful resource of publications from Canadian research institutions, government agencies, etc. All the materials in this collection are full-text.

Academic Honesty and Integrity

Faculty considers breaches of the Senate Policy on Academic Honesty to be serious matters. To quote the Senate Policy on Academic Honesty:

The Policy on Academic Honesty is a reaffirmation and clarification for members of the University of the general obligation to maintain the highest standards of academic honesty. It outlines the general responsibility of faculty to foster acceptable standards of academic conduct and of the student to be mindful of and abide by such standards.

Faculty members are encouraged to pursue suspected cases of academic dishonesty with formal charges.

PLAGIARISM is the misappropriation of the work of another by representing another person's ideas, writing or other intellectual property as one's own. This includes the presentation of all or part of another person's work as something one has written, paraphrasing another's writing without proper acknowledgement, or representing another's artistic or technical work or creation as one's own. Any use

of the work of others, whether published, unpublished or posted electronically, attributed or anonymous, must include proper acknowledgement.

Examples of Plagiarism:

- Quoting directly from a source without putting the material in quotation marks and providing a reference
- Paraphrasing from a source without providing a reference
- Submitting draft material that is not properly referenced

CHEATING is the attempt to gain an improper advantage in an academic evaluation.

Forms of cheating include:

- Obtaining a copy of an examination before it is officially available or learning an examination question before it is officially available;
- Copying another person's answer to an examination question;
- Consulting an unauthorized source during an examination;
- Disruption of an academic evaluation by any means;
- Obtaining assistance by means of documentary, electronic or other aids which are not approved by the instructor;
- Changing a score or a record of an examination result;
- Submitting the work one has done for one class or project to a second class, or as a second project, without the prior informed consent of the relevant instructors;
- Submitting work prepared in collaboration with another or other member(s) of a class when collaborative work on a project has not been authorized by the instructor;
- Submitting work prepared in whole or in part by another person and representing that work as one's own;
- Offering for sale essays or other assignments, in whole or in part, with the expectation that these works will be submitted by a student for appraisal;
- Preparing work in whole or in part, with the expectation that this work will be submitted by a student for appraisal.

Students who commit plagiarism or cheating usually receive a zero (0.0) on the assignment, test or examination. For a second offence the penalty may be failure in the course or even suspension from the University. The range of penalties are found at this [link](#).

Read the [university policy on academic honesty](#). Students must review the interactive on-line Tutorial on academic integrity at this [link](#) and then take a test at this [link](#).

Students may re-take the quiz as many times as they need to score 100%. Only then the test is considered complete and students can print a certificate. Students should print several copies of the results page, hand one in to the course instructor, and keep the extras with their own records in case it is required for another course. The certificate is valid for one year and students must re-take the quiz every year if required.

The Academic Integrity Online test must be completed and the results page submitted to the Course Director no later than the date of the final lecture.

ACCESS/DISABILITY

York provides services for students with disabilities (including physical, medical, learning and psychiatric disabilities) needing accommodation related to teaching and evaluation methods/materials. These services are made available to students in all Faculties and programs at York University.

Students in need of these services are asked to register with disability services as early as possible to ensure that appropriate academic accommodation can be provided with advance notice. You are encouraged to schedule a time early in the term to meet with each professor to discuss your accommodation needs. Please note that registering with disability services and discussing your needs with your professors is necessary to avoid any impediment to receiving the necessary academic accommodations to meet your needs.

Additional information is available at www.yorku.ca/disabilityservices or from disability service providers:

[Physical, Sensory & Medical Disability Services](#)

N108 Ross Building 416-736-5140

[Learning Disability Services](#)

W128 Bennett Centre for Student Services, 416-736-5383

[Mental Health Disability Services](#)

N110 Bennett Centre, 416-736-5297

[GLENDON STUDENTS - Counselling & Disability Services](#)

Glendon Hall, Room 111A, 416-487-6709

RELIGIOUS OBSERVANCE ACCOMMODATION

York University is committed to respecting the religious beliefs and practices of all members of the community, and making accommodations for observances of special

significance to adherents. Should any of the dates specified in this syllabus for an in-class test or examination pose such a conflict for you, contact the Course Director within the first three weeks of class. Similarly, should an assignment to be completed in a lab, practicum placement, workshop, etc., scheduled later in the term pose such a conflict, contact the Course director immediately. Please note that to arrange an alternative date or time for an examination scheduled in the formal examination periods (December and April/May), students must complete an online [Examination Accommodation Form](#), which can be obtained from Student Client Services, Student Services Centre.

STUDENT CONDUCT

Students and instructors are expected to maintain a professional relationship characterized by courtesy and mutual respect and to refrain from actions disruptive to such a relationship. Moreover, it is the responsibility of the instructor to maintain an appropriate academic atmosphere in the classroom, and the responsibility of the student to cooperate in that endeavour. Further, the instructor is the best person to decide, in the first instance, whether such an atmosphere is present in the class. A statement of the policy and procedures involving disruptive and/or harassing behaviour by students in academic situations is available at the following [link](#).

Please note that this information is subject to periodic update. For the most current information, please go to the [CCAS webpage](#) (see Reports, Initiatives, Documents).

LECTURE SCHEDULE

September 13, 2017

Seminar 1: Critical Approaches to Power: Power/Knowledge, Biopower, Power Relations and Sociology of Knowledge

Themes/Objectives: To examine three theoretical schools in brief – political economy (Farmer), post-structuralist approach to power (Manonkha's take on Foucault) and sociology of knowledge (Adams) – in order to assemble the tools to critically examine issues surrounding pharmaceutical policy, globalization, ethics and equity. These theories allow us to illuminate macro policy processes and products, as well as their micro effects as they are felt on the ground by individuals and communities in the Global South.

Readings:

Farmer, Paul

2004 An Anthropology of Structural Violence. *Current Anthropology* 45(3): 305-325.

Manonkha, Ivan

2009 Foucault's Concept of Power and the Global Discourse of Human Rights. *Global Society* 23(4): 429-452.

Adams, Vianne

2013 Evidence-Based Global Public Health: Subjects, Profits, Erasures, pp. 54-90. *In* When People Come First (Biehl and Petryna eds.). Princeton: Princeton University Press.

September 20, 2017

Seminar 2: Human Rights Frameworks and Access to Pharmaceuticals

Themes/Objectives: To introduce international policy frameworks outlining the right to health and access to medicines as presented by the United Nations system. Additionally, we will critically examine the implications of the judicialization (and, hence, pharmaceuticalization) of the right to health through a case study of Brazil.

Readings:

Khosla, Rajat, and Paul Hunt

2012 Human Rights Responsibilities of Pharmaceutical Companies in Relation to Access to Medicines, pp. 25-45. *In* Access to Medicines as a Human Right: Implications for Pharmaceutical Industry Responsibility (Forman and Kohler, eds.). Toronto: University of Toronto Press.

Alkoby, Asher

2012 Improving Access to Essential Medicines: International Law and Normative Change, pp. 46-74. *In* Access to Medicines as a Human Right: Implications for Pharmaceutical Industry Responsibility (Forman and Kohler, eds.). Toronto: University of Toronto Press.

Biehl, Joao, and Adriana Petryna

2013 Therapeutic Markets and the Judicialization of the Right to Health, pp. 325-346. *In* When People Come First (Biehl and Petryna eds.). Princeton: Princeton University Press.

September 27, 2017

Seminar 3 – Global Health Organizations and Pharmaceutical Policy

Themes/Objectives: To gain a thorough understanding of the strengths and weaknesses of WHO policies and practices concerning essential medicines as the organization shifts from an emphasis on MDGs to SDGs. Furthermore, we will critically examine related World Bank policies and programming through an in-depth case study of pharmaceutical policy reforms in Latin America.

Readings:

World Health Organization

2017 Towards Access 2030: WHO Essential Medicines and Health Products Strategic Framework 2016-2030. Geneva: World Health Organization.

Available at:

http://www.who.int/medicines/publications/Towards_Access_2030_for_web.pdf?ua=1

Laing, Richard, Brenda Waning, Andy Gray, Nathan Ford, Ellen 't Hoen
2003 25 Years of the WHO Essential Medicines Lists: Progress and Challenges.
Lancet 361: 1723-29.

Attaran, Amir et al
2006 The World Bank: False Financial and Statistical Accounts and Medical
Malpractice in Malaria Treatment. Lancet 368: 247-52.

Homedes, Nuria, Antonio Ugalde, and Joan Rovira Forns
2005 The World Bank, Pharmaceutical Policies, and Health Reforms in Latin
America. International Journal of Health Services 35(4): 691-717.

October 4, 2017

Seminar 4: Public Private Partnerships (PPPs)

Themes/Objectives: To critically examine the emergence of the transnationalist class, power re-configurations in global health governance with the advent of PPPs and the re-formulation of neoliberalism across global health architecture through a review of the Bill and Melinda Gates Foundation and their offshoot, GAVI, as well as the Global Fund.

Readings:

McNeill, Desmond, and Kristin Ingstad Sandberg
2014 Trust in Global Health Governance: The GAVI Experience. Global Governance
20:325-343.

Harman, Sophie
2016 The Bill and Melinda Gates Foundation and Legitimacy in Global Health
Governance. Global Governance 22:349-368.

Davis, Sara
2014 Human Rights and the Global Fund to Fight AIDS, Tuberculosis, and Malaria.
Health and Human Rights 16(1): 134-148.

Brown, Garrett Wallace
2009 Multisectoralism, Participation and Stakeholder Effectiveness: Increasing the
Role of Nonstate Actors in the Global Fund to Fight AIDS, Tuberculosis, and Malaria.
Global Governance 15(2): 169-177.

October 11, 2017

Seminar 5 – Clinical Trials in the Global South

Themes/Objectives: To critically unpack the internationalization of clinical trials, including ethical and regulatory environments, unequal social contexts, conditions of inequality where research is carried out and the re-production of a “global geography of human experimentation” (Petryna 2007:33).

Readings:

*Petryna, Adriana

2007 Globalizing Human Subjects Research, pp. 33-60. *In* Global Pharmaceuticals: Ethics, Markets, Practices, Petryna, Lakoff and Kleinman, eds. Durham: Duke University Press.

Global Health Watch

2014 Global Health Watch 4: An Alternative World Health Report. London, UK: Zed Books. Available at:
http://www.ghwatch.org/sites/www.ghwatch.org/files/D7_0.pdf.

Homedes, Nuria, and Antoni Ugalde

2015 Availability and Affordability of New Medicines in Latin American Countries Where Pivotal Clinical Trails Were Conducted. *Bulletin of the World Health Organization* 93:674-683.

Pasquali, Sara, Danielle Burstein, Daniel Benjamin, P. Brian Smith, and Jennifer Li

2010 Globalization of Pediatric Research: Analysis of Clinical Trials Completed for Pediatric Exclusivity. *Pediatrics* 126 (3): e687-e692.

October 18, 2017**Seminar 6 – Drug Promotion Across the Globe**

Themes/Objectives: To critically work through big pharma's global expansion strategies by considering the frictions between science, commerce and ethics. Moreover, we will unearth how the accompanying marketing strategies play out within localized contexts through case studies situated in Japan and India.

Readings:

*Applbaum, Kalman

2007 Educating for Global Mental Health: The Adoption of SSRIs in Japan, pp. 85-110. *In* Global Pharmaceuticals: Ethics, Markets, Practices, Petryna, Lakoff and Kleinman, eds. Durham: Duke University Press.

Lexchin, Joel

2012 Social Responsibility and Marketing of Drugs in Developing Countries: A Goal or an Oxymoron? pp. 124-147. *In* Access to Medicines as a Human Right: Implications for Pharmaceutical Industry Responsibility (Forman and Kohler, eds.). Toronto: University of Toronto Press.

Ecks, Stephan, and Ian Harper

2013 Public-Private Mixes: The Market for Anti-Tuberculosis Drugs in India, pp. 252-275. *In* When People Come First (Biehl and Petryna eds.). Princeton: Princeton University Press.

October 25, 2017

Seminar 7 – Intellectual Property Rights – TRIPS, the Doha Declaration and HIV/AIDS

Themes/Objectives: To critically review intellectual property frameworks, WTO agreements and TRIPS mechanisms with the view of examining, historically and in a contemporary context, worldwide access to ARVs in the fight against HIV/AIDS.

Readings:

Ayres, J., and P. Siplon

2007 Divergent Campaigns Toward Global Health Governance: Canadian and US Approaches to the HIV/AIDS pandemic. *Canadian-American Public Policy* 69:1 (is an electronic publication so page numbers not offered).

Kolawole Oke, Emmanuel

2013 Incorporating a Right to Health Perspective into the Resolution of Patent Law Disputes. *Health and Human Rights* 15(2): 97-109.

Weber, Ashley, and Lisa Mills

2010 A One-Time-Only Combination: Emergency Medicine Exports under Canada's Access to Medicines Regime. *Health and Human Rights* 12(1): 109-122.

Reynolds Whyte, Susan, Michael Whyte, Lotte Meinert, and Jennifer Twebaze

2013 Belonging in Uganda's Projectified Landscape of AIDS Care, pp. 140-165. *In When People Come First* (Biehl and Petryna eds.). Princeton: Princeton University Press.

November 1, 2017

Seminar 8 – Case Study I: Vaccines - Controversies and Access

Themes/Objectives: To critically examine how global vaccination programs are delivered through vertical health programming distorting the priorities of localized health systems in the Global South. Moreover, newer, expensive vaccine technologies, like the HPV vaccine, are available in abundance in the developed world, but global health organizations have been slow to offer them in developing countries, where they are needed most. We will examine this disparity and the challenges of delivering new vaccine technologies to those most at-risk.

Readings:

Hardon, Anita, and Stuart Blume

2005 Shifts in Global Immunisation Goals (1984-2004): Unfinished Agenda and Mixed Results. *Social Science & Medicine* 60:345-356.

Carpenter, Laura, and Monica Casper

2009 Global Intimacies: Innovating the HPV Vaccine for Women's Health. *Women's Studies Quarterly* 37: 1&2 (Spring & Summer): 80-100.

Sathyamala, C., Onkar Mittal, Rajib Dasgupta, and Ritu Priya

2005 Polio Eradication Initiative in India: Deconstructing the GPEI. *International Journal of Health Services* 35(2): 361-383.

Yamada, Tadataka

2009 Poverty, Wealth, and Access to Pandemic Influenza Vaccines. *The New England Journal of Medicine* 361(12): 1129-1131.

November 8, 2017

Seminar 9 – Case Study II: Global Mental Health Policy and Pharmaceuticals

Themes/Objectives: As mental health has become a priority among international health agencies how are they incorporating pharmaceuticals and their access into policy and programs? Does this policy shift forgo addressing social determinants of health? Han's case study, based in Santiago Chile, provides context to, and insight into the complexities, of implementing vertical interventions without strong horizontal health programming foundations.

Readings:

World Health Organization

2005 Improving Access and Use of Psychotropic Medicines. Geneva: Author.

Available at:

http://www.who.int/mental_health/policy/improving_access_final_10_01_05.pdf

Han, Clara

2013 Labor Instability and Community Mental Health: The Work of Pharmaceuticals in Santiago, Chile, pp. 276-301. *In* When People Come First (Biehl and Petryna eds.). Princeton: Princeton University Press.

November 15, 2017

Seminar 10 - Case Study III: Pain Management & Palliative Care in the Global South

Themes/Objectives: As cancer morbidity and mortality is increasing in the Global South, which policy measures are being put into place to ensure dignified and ethical treatments of those who are ill with, and dying of, cancer in the Global South? The appalling lack of opioid analgesics for treatment and palliative care in the Global South works in stark contrast to the overabundance of such drugs in the Global North, particularly as is being experienced in the opioid epidemic in Canada.

Reading:

Human Rights Watch

2011 Global State of Pain Treatment: Access to Palliative Care as a Human Right.

New York: Author. Please read chapters I, II, III, IV, VII and IX only. Available at:

<https://www.hrw.org/sites/default/files/reports/hhr0511W.pdf>

Livingston, Julie

2013 The Next Epidemic: Pain and the Politics of Relief in Botswana's Cancer Ward, pp. 182-206. *In* When People Come First (Biehl and Petryna eds.). Princeton: Princeton University Press.

November 22, 2017

Seminar 11 – Drug Regulatory Systems & Post-Market Surveillance

Themes/Objectives: To critically examine drug regulatory systems across the world, including contrasting case studies involving Canada and countries in Europe and sub-Saharan Africa, by focusing upon issues of policy process, regulatory frameworks and post-market surveillance and safety.

Readings:

Wyndham-West, Michelle, Mary Wiktorowicz, and Peter Tsasis
2017 (Early access article posted January 16). Power and Culture in Emerging Medical Technology Policymaking: The Case of the HPV Vaccine in Canada. *Evidence & Policy* (Policy Press, University of Bristol, pp. 1-23). Article is available on course director's ResearchGate profile.

Wiktorowicz, Mary, Joel Lexchin, and Kathy Moscou
2012 Pharmacovigilance in Europe and North America: Divergent Approaches. *Social Science and Medicine* 75:165-170.

World Health Organization
2010 Assessment of Medicines Regulatory Systems in Sub-Saharan African Countries. Geneva: Author. Available at <http://apps.who.int/medicinedocs/en/d/Js17577en/>.

November 29, 2017

Seminar 12 – Potential Policy Solutions to Unequal Drug Access: Health Impact Fund, Patent Pools and Open Source Drug Discovery

Themes/Objectives: As we are now familiar with the challenges inherent in existing pharmaceutical policies across global institutions, agencies and PPPs vis-à-vis equity, ethics and access where do we go from here? We will mull over potential policy solutions in terms of the proposed Health Impact Fund, patent pools, and open source drug discovery. These proposed policy solutions may also engender hybridized or new ideas/models for global drug access equity and we will discuss such potential policy options in our final class.

Readings:

*Pogge, Thomas
2010 The Health Impact Fund: Better Pharmaceutical Innovations at Much Lower Prices. *In* Incentives for Global Public Health: Patent Law and Access to Essential Medicines (pp. 135 -154). Cambridge: Cambridge University Press.

*Nicol, Dianne, and Jane Nielsen

2010 Opening the Dam: Patent Pools, Innovation, and Access to Essential Medicines. *In Incentives for Global Public Health: Patent Law and Access to Essential Medicines* (pp. 235-262). Cambridge: Cambridge University Press.

*Srinivas, Krishna Ravi

2010 Open Source Drug Discovery: A Revolutionary Paradigm or a Utopian Model? *In Incentives for Global Public Health: Patent Law and Access to Essential Medicines* (pp. 263-283). Cambridge: Cambridge University Press.