

**CARLETON UNIVERSITY**

Carleton University acknowledges the location of its campus on the unceded and unsundered territories of the Algonquin Anishinabeg people.

**SCHOOL OF PUBLIC POLICY AND ADMINISTRATION  
And INSTITUTE OF POLITICAL ECONOMY**

**PADM 5702 / PECO 5502: Policy Seminar****Political Economy of Pharmaceuticals**

**SYLLABUS Winter 2025**

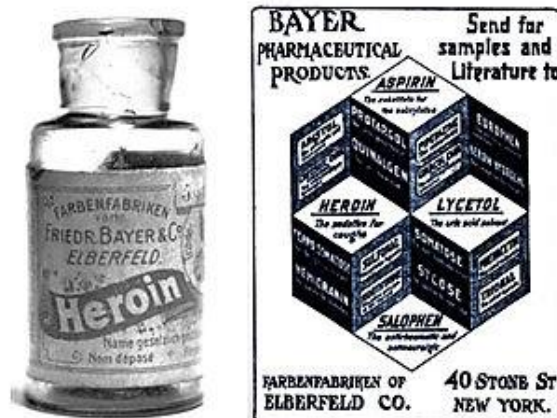
<b>Instructor:</b>	Marc-André Gagnon	<b>Class:</b>	Mon 14:35-17:25 Room RB-3201
<b>Office:</b>	River Building-5201	<b>Dates:</b>	January 6 - April
<b>Telephone:</b>	(613) 520-2600 ext. 1690	<b>Office Hours:</b>	Mondays: 12:30-13:30
<b>E-Mail:</b>	<a href="mailto:ma.gagnon@carleton.ca">ma.gagnon@carleton.ca</a>	<b>Brightspace link:</b>	<a href="http://www.brightspace.carleton.ca">www.brightspace.carleton.ca</a>

**I. COURSE DESCRIPTION AND PURPOSE**

Medicines have become a central element of health care services. Representing around 2% of Canadian GDP, prescription drugs are often found in the media headlines: safety issues, lack of access, potential breakthrough innovation, record corporate fines, regulatory failures, adverse effects, abusive pricing, cost-containment measures, disease mongering, overmedication, conflicts of interests, mergers and acquisitions, shortages, rare diseases, neglected diseases, patent issues, opioid crisis, medicalization of life, etc... At the intersection of business, medicine, public policy and health administration, the pharmaceutical sector has an important impact in the daily lives of a majority of Canadians. The global pharmaceutical sector is the most regulated sector, and it is also one of the most profitable industrial sectors year after year. This graduate seminar analyzes the political economy of the pharmaceutical sector, from the research lab to the bedside of patients. It analyzes regulation, innovation, business models, access to medicines, corruption and ethical issues.

This course aims at offering a broad perspective of a specific sector in the knowledge-based economy in order to better grasp the structural transformations at work in an economy built on the production of knowledge.

The course analyzes the economic structures of the pharmaceutical sector and the dominant business models at work, the regulatory framework from approval of new drugs to reimbursement, the challenges of research and development and the impacts of innovation policies, debates over the institutional corruption of medical research, corporate strategies to influence prescribing habits, access to medicines in developed and developing countries, orphan drug policy as well as potential strategies to expand access to medicines, improve health outcomes and reduce costs. This course is trans-disciplinary, building on political economy, economics of innovation, health care policy, epidemiology, sociology of science and industrial organization.



### Required Textbooks:

Joel Lexchin, *Private Profit and Public Policy; The pharmaceutical Industry and the Canadian State*, Toronto: University of Toronto Press, 2016. Available at University of Toronto Press Bookstore (43\$). Also available for free on Carleton library website.

Sergio Sismondo, *Ghost-Managed Medicine: Big Pharma's Invisible Hands*. Manchester: Mattering Press, 2018. The book is available online for free: <https://www.matteringpress.org/books/ghost-managed-medicine>

## II. Competencies

By the end of the course, you will be able to:

- Identify the main areas of pharmaceutical policy and the main issues relating to the political economy of the pharmaceutical sector.
- Understand and explain the fundamental features of the socio-historical evolution of the pharmaceutical sector, and more specifically the transformations due to the emergence of the knowledge-based economy.
- Identify key aspects and weaknesses of the major paradigms as well as the inter-paradigmatic debates over pharmaceutical policy.
- Grasp the core issues surrounding the debates over the implementation of public drug coverage.
- Have a clear understanding of the workings and regulations of the whole supply chain for prescription drugs, from basic research for new active substances to reimbursement policies.
- Have a clear understanding of the current challenges concerning pharmaceuticals: Innovation for neglected diseases, orphan drugs for rare diseases, cost-containment measures, disease mongering, corrupted corporate practices.
- Navigate more easily relevant statistical resources and literature, including economic indicators and medical literature.
- Have a critical understanding of the impact of conflicts of interests between healthcare professionals and the pharmaceutical industry.

### III. Course Expectations

**Pedagogical Approach:** The course will be not only based on lectures by the Professor, but also on seminars surrounding the reading material. Students are expected to have carefully read the required readings for each class, and to come prepared to discuss them. While the required readings are sometimes substantial, no additional reading is required to satisfy the course requirements.

A mark in the A range would be given to a student who attends all classes, regularly contributes, whose contributions indicate familiarity with the reading material, and an ability to ask questions and discuss examples that show insight into the material. At each class, I will give you questions to guide your thinking, reading and participation for the following week.

**Student Workload:** The workload expectation in terms of hours is an average of 8-9 hours/week. Depending upon the format for particular weeks, three of those are “classroom” hours. Five to six hours/week (on average across the term) will be spent outside-the-class – posting comments for on-line discussion, weekly readings, preparation for presentations and other in-class work, assignments, and research. At minimum, you should be spending three hours per week on the readings assigned per week. The readings have been selected with these time allocations in mind.



"You are completely free to carry out whatever research you want, so long as you come to these conclusions."

### IV. Course Requirements

Participation	10%
Analysis of a specific drug or vaccine: nature, market, risks/benefits	20%
Analysis of a public drug plan: Description and evaluation	20%
Outline for the term paper	10%
Term Paper	40%

### ***Participation***

Students are expected to do all the readings and come prepared to all classes. Participation will be based on attendance and contribution to class discussion during seminars.

***Presentation of a specific drug:*** The student chooses one drug or vaccine and analyzes possible controversies surrounding the product. The student must identify the drug (what it was approved for and what it does), identify the markets for that drug and assess the economic importance of the drug and present the risks/benefits of the drugs. Some of the drugs that could be presented are: Remicade, Humira, Sovaldi, Procystis, Strensiq, Soliris, Zyprexa, Seroquel, Paxil, Dabigatran, Tamiflu, Avastin, Lipitor, Crestor, Zocor, Vytorin, Actonel, Nexium, Plavix, Gardasil, Singulair, or any other relevant drug (to be discussed with the professor).

***Presentation of a public drug plan:*** The student analyzes one public drug plan (provincial/federal/foreign). The student presents details of that drug plan (what is covered, for whom, co-pays) and analyzes the efficiency of the drug plan based on different criteria.

### ***Outline for term paper***

On Class 11, the student must hand in a one page presentation of the topic on which he would like to work on for the term paper, and the possible angles from which he would like to tackle the issue. Identify the research question and the main ideas you will be developing. There is flexibility in terms of topic, the student can choose an issue in pharmaceutical policy that is not directly covered in class.

### ***Term papers***

The term paper should be around 20 pages, and include a bibliography (use *Chicago Manual of Style* or *APA* to make sure your references are respecting standards).

The term paper must include an introduction, a development, and a conclusion. The introduction normally represents 10% of the essay. It must: 1-introduce the topic, 2-introduce the research question about the topic and 3-announce how the author will tackle the issue (First, the essay will explore... Second the essay will address... etc...). The conclusion must summarize the main idea of the essay and, preferably, should open up on wider perspectives.

All references used must be listed in the bibliography. Extensive references to the reading material in class is required. A relevant guide about how to write essays is Babington, Doug and Don LePan *The Broadview Guide to Writing*, Revised 4<sup>th</sup> Canadian Edition (Peterborough: Broadview Press, 2016).

The use of ***generative artificial intelligence tools (e.g. ChatGPT)*** is not permitted to generate assessed content, but can be use as a supporting tool for example for copy-editing papers. If such tool is used at any step of the writing process (from research to copy-editing), you must include an appendix detailing all prompts used with such tool. The instructor reserves the right to interview students with respect to their submitted works to assess the student's level of understanding with the submitted work.

**V. SEMINAR SCHEDULE (tentative):**

Class 1 (January 6): Introduction and Overview

Class 2 (January 13): Mapping the history and the political economy of the pharmaceutical sector.

Class 3 (January 20): Risks and Benefits: Corporate Ghost-management of Medical Research

Class 4 (January 27): Drug Safety and Regulatory Process for the Approval of New Drugs (Health Canada)

Class 5 (February 3): Patent Policy and Innovation: The Canadian Path.

\*Submission of the analysis of a specific drug (February 6)

Class 6 (February 10): Drug Coverage and Access to Medicines in Canada: The Great Pharmacare Debate

\*READING WEEK

Class 7 (February 24): Drug prices and therapeutic value: Understanding health technology assessment

Class 8 (March 3): Rare diseases, Orphan drugs, Biologics, Biosimilars, Gene therapies & Nichebusters

\* Submission of the analysis of a public drug plan (March 6)

Class 9 (March 10): Financialized Business Models and Pricing in the Pharmaceutical Sector.

Class 10 (March 17): Global Access to Essential Medicines. Patent monopoly in the era of free-trade.

Class 11 (March 24): The Covid-19 vaccine debacle: A Pandemic meets financialized capitalism.

\*Submission of the outline for the term paper (March 24)

Class 12 (March 31): Rethinking Pharma: Looking for alternatives

Class 13 (April 7): Conclusion

\*Submission of term paper (April 16)

## VI. Reading Material and Seminar Schedule (all subject to change):

### Class 1: Introduction and Overview.

Identification of the main issues and challenges in the pharmaceutical sector.

#### **Reading Material:**

Joel Lexchin. *Private Profits versus Public Policy*. Toronto: University of Toronto Press, 2016: Introduction pp.3-12.

Sergio Sismondo, *Ghost-Managed Medicine: Big Pharma's Invisible Hands*. Manchester: Mattering Press, 2018: pp.7-27: <https://www.matteringpress.org/wp-content/uploads/2018/07/Sismondo-Ghost-managed-Medicine-2018-1.pdf>

Gagnon, MA, 2024. "The anatomy of Big Pharma". In Primrose D, Loeppky Rand Chang R. (eds) *The Routledge Handbook of the Political Economy of Health and Healthcare*. London and New York: Routledge: pp.245-258.

### Class 2: Mapping the history and the political economy of the pharmaceutical sector.

Structures of the sector. Therapeutic Revolution /Marketing Revolution/Emergence of the Knowledge-Based Economy.

#### **Reading Material:**

Marc-André Gagnon. *The Nature of Capital in the Knowledge-Based Economy; The Case of the Global Pharmaceutical Industry*. Chapters 4: pp.122-196.

Peter Drahos and John Braithwaite. *Information Feudalism*. Sterling: Earthscan, 2002 (Read Chapter 4 Stealing from the Mind, pp. 61-73): <http://johnbraithwaite.com/wp-content/uploads/2016/06/Information-Feudalism-Who-Own.pdf>

Luigi Orseniggo, Giovanni Dosi and Mariana Mazzucato. "The Dynamics of Knowledge Accumulation, Regulation and Appropriability in the Pharma Biotech Sector: Policy Issues". Chapter 14 from Mariana Mazzucato and Giovanni Dosi (eds). *Knowledge Accumulation and Industry Evolution; The Case of Pharma Biotech*. Cambridge: Cambridge University Press, 2006: pp.402-431.

### Class 3: Risks and Benefits of Prescription drugs: The Ghost Management of Medical Research?

Debate on the Institutional Corruption of medicine, disease mongering and off-label promotion

#### **Reading Material:**

Sergio Sismondo, *Ghost-Managed Medicine: Big Pharma's Invisible Hands*. Manchester: Mattering Press, 2018: Read Chapters 2,3,6: pp.40-90; 139-160: <https://www.matteringpress.org/wp-content/uploads/2018/07/Sismondo-Ghost-managed-Medicine-2018-1.pdf>

Donald Light "Bearing the Risks of Prescription Drugs" In *The Risks of Prescription Drugs*. Columbia University Press 2010: pp.1-39.

Gagnon, Marc-André. "The political economy of influence: Ghost-Management in the Pharmaceutical Sector", in Katherine Fierlbeck et al. *Transparency, Power, and Influence in the Pharmaceutical Industry; Policy Gain or Confidence Gain*: University of Toronto Press, 2021: pp. 159-183.

MOYNIHAN, Ray. "Key Opinion Leaders: Independent Experts or Drug Representatives in Disguise?" *British Medical Journal* 336 (2008): 1402-3.

#### **Class 4: Drug Safety and Regulatory Process for the Approval of New Drugs (Health Canada);**

Understanding the Role of Health Canada and the Food and Drug Administration.

##### **Reading Material:**

Prescrire. Drugs in 2023: A Brief review. *Prescrire International*. April 2024.

Joel Lexchin. *Private Profits versus Public Policy*. Toronto: University of Toronto Press, 2016: Read Chapters 2,3,5: pp.34-80; 112-134.

Marc-Andre Gagnon, Matthew Herder, Janice Graham, Katherine Fierlbeck and Anna Danyliuk, 2021. "Clinical trial data transparency in Canada: Mapping the Progress from Laggard to Leader". Chapter from Katherine Fierlbeck, Janice Graham and Matthew Herder (eds.) *Transparency, Power, and Influence in the Pharmaceutical Industry*. Toronto: University of Toronto Press: pp. 114-128.

Canadian Health Policy Institute (2024). Waiting for new medicines in Canada, Europe, and the United States 2018-2023. Canadian Health Policy.

Take an hour to browse the Health Canada website on the regulation of drug products:

<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products.html>

#### **Class 5: Patent Policy and Innovation: The Canadian Path.**

Critical Analysis of the impact of patents on innovation. Understanding the R&D dynamics in the Canadian Pharmaceutical sector.

##### **Reading Material:**

Joel Lexchin. *Private Profits versus Public Policy*. Toronto: University of Toronto Press, 2016: Read Chapters 6: pp.135-156; Chapter 8: pp.184-207.

Paul Grootendorst, Aidan Hollis and Aled Edwards. "Patents and Other Incentives for Pharmaceutical Innovation" in *Encyclopaedia of Health Economics*. London: Elsevier, 2014.

Patented Medicines Price Review Board. *Annual Report 2023*. Ottawa: PMPRB, 2024.

OPTIONAL: Frank Lichtenberg. *The Benefits of Pharmaceutical Innovation: Health, Longevity, and Savings*. Montreal: Montreal Economic Institute, June 2016.

#### **CLASSES 6-13 : TBA**

## VII. MARKING SCALE

Particularly if written assignments or term papers are to be used as formal graded requirements, then provide the SPPA Grading Guidelines as below. These Guidelines suggest B+ to be the average level of performance.

Letter grade	CU grade points	Indicates that work is:	% Range	SPPA Explanation
A+	12	Outstanding	90-100	For written work, virtually publishable. Demonstrates exceptional evaluative judgment, outstanding critical thinking, and mastery of technical as well as literary aspects of writing.
A	11	Excellent	85-89	Demonstrates superior grasp of material, very strong critical thinking, and capacity to understand and extend underlying patterns.
A-	10	Very Good	80-84	Demonstrates strong grasp of material, its component parts, and capacity to analyze their relationships to each other.
B+	9	Good	77-79	Demonstrates clear understanding of material and ability to apply concepts. Written work is competent.
B	8	Satisfactory	73-76	Satisfactory, but below average. Demonstrates comprehension of material, reasonable but not strong analytical capacity, with some limitations in the ability to apply concepts.
B-	7	Barely Adequate	70-72	Clearly below average. Demonstrates comprehension and understanding, with limited capacity for application. Communication skills problematic.
C+	6	Less Than Adequate	67-69	Did not demonstrate an adequate understanding of the material or the ability to apply the concepts. Writing and/or presentations show serious problems.
C to D-			50-66	Grades in this range indicate work that is passable in some respects but does not meet the standards of graduate work.
F			Failure	Did not meet minimal requirements.

## VIII. UNIVERSITY POLICIES

### STUDENT RIGHTS AND RESPONSIBILITIES

Carleton University strives to provide a safe environment conducive to personal and intellectual growth, free of injustice and characterized by understanding respect, peace, trust, and fairness. The Student Rights and Responsibilities at Carleton University are available [HERE](#).

### ACADEMIC INTEGRITY

Please be aware that all work submitted as a requirement for this course must be both your own work and consistent to this course. Academic offences are serious infractions and will not be tolerated.

#### Plagiarism:

The University Academic Integrity Policy defines plagiarism as *“presenting, whether intentionally or not, the ideas, expression of ideas or work of others as one’s own.”* This includes reproducing or paraphrasing portions of someone else’s published or unpublished material, regardless of the source,



and presenting these as one's own without proper citation or reference to the original source. Examples of sources from which the ideas, expressions of ideas or works of others may be drawn from include but are not limited to: books, articles, papers, literary compositions and phrases, performance compositions, chemical compounds, art works, laboratory reports, research results, calculations and the results of calculations, diagrams, constructions, computer reports, computer code/software, material on the internet and/or conversations.

Examples of plagiarism include, but are not limited to:

- any submission prepared in whole or in part, by someone else;
- using ideas or direct, verbatim quotations, paraphrased material, algorithms, formulae, scientific or mathematical concepts, or ideas without appropriate acknowledgment in any academic assignment;
- using another's data or research findings without appropriate acknowledgement;
- submitting a computer program developed in whole or in part by someone else, with or without modifications, as one's own; and
- failing to acknowledge sources through the use of proper citations when using another's work and/or failing to use quotations marks.

Plagiarism is a serious offence that cannot be resolved directly by the course's instructor. The Associate Dean of the Faculty follows a rigorous [process for academic integrity allegations](#), including reviewing documents and interviewing the student, when an instructor suspects a violation has been committed. Penalties for violations may include a final grade of "F" for the course.

**Intellectual Property:** Classroom teaching and learning activities, including lectures, discussions, presentations, etc. – by both instructors and students – are copy protected and remain the intellectual property of their respective author(s). All course materials, including PowerPoint presentations, outlines, and other materials, are also protected by copyright and remain the intellectual property of their respective author(s).

Students registered in the course may take notes and make copies of course materials for their own educational use only. Students are not permitted to reproduce or distribute lecture notes and course materials publicly for commercial or non-commercial purposes without express written consent from the copyright holder(s).

## IX. STATEMENT ON STUDENT MENTAL HEALTH

As a student you may experience a range of mental health challenges that significantly impact your academic success and overall well-being. If you need help, please speak to someone. There are numerous resources available both on- and off-campus to support you. For more information, please consult <https://wellness.carleton.ca/>.

#### Emergency Resources (on and off campus)

- Suicide Crisis Helpline: call or text 9-8-8, 24 hours a day, 7 days a week.
- For immediate danger or urgent medical support: call 9-1-1

#### Carleton Resources

- Mental Health and Wellbeing: <https://carleton.ca/wellness/>
- Health & Counselling Services: <https://carleton.ca/health/>
- Paul Menton Centre: <https://carleton.ca/pmc/>
- Academic Advising Centre (AAC): <https://carleton.ca/academicadvising/>
- Centre for Student Academic Support (CSAS): <https://carleton.ca/csas/>
- Equity & Inclusivity Communities: <https://carleton.ca/equity/>

#### Off Campus Resources

- Distress Centre of Ottawa and Region: call 613-238-3311, text 343-306-5550, or connect online at <https://www.dcottawa.on.ca/>
- Mental Health Crisis Service: call 613-722-6914 or toll-free 1-866-996-0991, or connect online at <http://www.crisisline.ca/>
- Empower Me Counselling Service: call 1-844-741-6389 or connect online at <https://students.carleton.ca/services/empower-me-counselling-services/>
- Good2Talk: call 1-866-925-5454 or connect online at <https://good2talk.ca/>
- The Walk-In Counselling Clinic: for online or on-site service <https://walkincounselling.com>

## **X. ACADEMIC ACCOMMODATIONS**

Carleton is committed to providing academic accessibility for all individuals. You may need special arrangements to meet your academic obligations during the term. The accommodation request processes, including information about the *Academic Consideration Policy for Students in Medical and Other Extenuating Circumstances*, are outlined on the Academic Accommodations website ([students.carleton.ca/course-outline](https://students.carleton.ca/course-outline)).

You may need special arrangements to meet your academic obligations during the term. For an accommodation request the processes are as follows:

**Pregnancy obligation:** write to me with any requests for academic accommodation during the first two weeks of class, or as soon as possible after the need for accommodation is known to exist. For accommodation regarding a formally-scheduled final exam, you must complete the [Pregnancy Accommodation Form](#).

**Religious obligation:** write to me with any requests for academic accommodation during the first two weeks of class, or as soon as possible after the need for accommodation is known to exist. For more details [click here](#).

**Academic Accommodations for Students with Disabilities:** The Paul Menton Centre for Students with Disabilities (PMC) provides services to students with Learning Disabilities (LD), psychiatric/mental health disabilities, Attention Deficit Hyperactivity Disorder (ADHD), Autism Spectrum Disorders (ASD), chronic medical conditions, and impairments in mobility, hearing, and vision. If you have a disability requiring academic accommodations in this course, please contact PMC at 613-520-6608 or [pmc@carleton.ca](mailto:pmc@carleton.ca) for a formal evaluation. If you are already registered with the PMC, contact your PMC coordinator to send me your Letter of Accommodation at the beginning of the term, and no later than two weeks before the first in-class scheduled test or exam requiring accommodation (if applicable). After requesting accommodation from PMC, meet with me to ensure accommodation arrangements are made. Please consult the PMC website for the deadline to request accommodations for the formally-scheduled exam (if applicable).

**Survivors of Sexual Violence:** As a community, Carleton University is committed to maintaining a positive learning, working and living environment where sexual violence will not be tolerated, and where survivors are supported through academic accommodations as per Carleton's Sexual Violence Policy. For more information about the services available at the university and to obtain information about sexual violence and/or support, visit: <https://carleton.ca/equity/sexual-assault-support-services>

**Accommodation for Student Activities:** Carleton University recognizes the substantial benefits, both to the individual student and for the university, that result from a student participating in activities beyond the classroom experience. Reasonable accommodation will be provided to students who compete or perform at the national or international level. Write to me with any requests for academic accommodation during the first two weeks of class, or as soon as possible after the need for accommodation is known to exist. <https://carleton.ca/senate/wp-content/uploads/Accommodation-for-Student-Activities-1.pdf>

## XI. ANTI-RACISM, EQUITY, DIVERSITY AND INCLUSION

An inclusive and transformational university culture requires an environment free from discrimination, harassment and sexual violence where Indigenous ways of knowing and learning inform our systems and practices, and where equitable access to services and opportunities guides all university action. For confidential inquiries related to harassment, discrimination and

Accommodation response, please contact [equity@carleton.ca](mailto:equity@carleton.ca).

**SPPA Statement on Anti-Racism** <https://carleton.ca/sppa/sppa-statement-against-racism/>  
**Carleton University's Equity, Diversity and Inclusion (EDI) Action Plan,**  
**Indigenous Strategy** [Kinàmàgawin](#),

#### **Indigenous studies at SPPA**

Students who wish to learn more about Indigenous programming in the School and at Carleton are encouraged to contact Sheila Grantham, program administrator and community outreach coordinator, Indigenous Policy and Administration. [Sheila.Grantham@carleton.ca](mailto:Sheila.Grantham@carleton.ca). Also, for information about Carleton's Centre for Indigenous Initiatives and the *Ojigkwanong Indigenous Student Centre* (Patterson Hall 228), please visit <https://carleton.ca/indigenous/>.

**Addressing Human Rights Concerns:** The University and all members of the University community share responsibility for ensuring that the University's educational, work and living environments are free from discrimination and harassment. Should you have concerns about harassment or discrimination relating to your age, ancestry, citizenship, colour, creed (religion), disability, ethnic origin, family status, gender expression, gender identity, marital status, place of origin, race, sex (including pregnancy), or sexual orientation, please contact the [Department of Equity and Inclusive Communities](#) at [equity@carleton.ca](mailto:equity@carleton.ca).