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# Submission to the House of Commons Standing Committee on Science and Research's Study on Support for the Commercialization of Intellectual Property

**Authors:** Justin Mendoza, Amanda Frederiksen Leloup, Celine Huang

*This brief will outline the role of federally funded university health research in Canada today, the importance of access-oriented and equity-informed biomedical research and development policies, and UAEM's recommendations to maximize the impact and accessibility of health technologies worldwide through the commercialization of intellectual property.*

## Introduction

Higher education, which leads Canada's national research and innovation system[1], has a significant impact on the country's biomedical research products and how accessible those products ultimately become. The OECD reports that the higher education sector made up 41.25% of Canada's gross domestic expenditure for research and development (R&D) in 2017, with natural sciences research accounting for over 75% — a figure that has grown year-over-year since 1990[2]. Further, the U15 universities report that they altogether conduct approximately 8.5 billion dollars worth of research annually, comprising 79% of all competitively allocated research funding in Canada[3]. Given that the majority of Canadian biomedical research is conducted by universities, these institutions are uniquely positioned to influence the accessibility of the health technologies they research, develop, and license. Further, universities hold a pivotal role in the commercialization of the biomedical health technologies they develop given their position as foundational sites for the development of novel health technologies, allowing them to patent and own intellectual property rights for these technologies, which gives them control over both licensing and commercialization[4].

Licenses of this nature ordinarily serve solely as sources of revenue for universities, and yet they have the potential to be a pivotal point in increasing access to medicines on a global scale. At this licensing step, provisions can be included to increase drug access, as seen with the University of British Columbia's licensing of the low-cost formulation of Amphotericin B. Amphotericin B, which itself was licensed in a way to promote access in lower- and middle-income countries[5].

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[1] Bégin-Caouette, Olivier, Glen A. Jones, Grace Karram Stephenson, and Amy Scott Metcalfe. "Canada: The Role of the University Sector in National Research and Development." In *The Changing Academy – The Changing Academic Profession in International Comparative Perspective*, 375–92. Cham: Springer International Publishing, 2021.

[2]Bégin-Caouette, Olivier, Glen A. Jones, Grace Karram Stephenson, and Amy Scott Metcalfe. 2021. "Canada: The Role of the University Sector in National Research and Development." In The Changing Academy – The Changing Academic Profession in International Comparative Perspective, 375–92. Cham: Springer International Publishing..

[3] U15 Group of Canadian Research Universities. "About Us," July 27, 2022. https://u15.ca/about-us/.

[4] Drozdoff V, Fairbairn D. Licensing biotech intellectual property in university-industry partnerships. Cold Spring Harb Perspect Med [Internet]. 2015 [cited 2023 Feb 24];5(3):a021014. Available from: http://dx.doi.org/10.1101/cshperspect.a021014

[5] Herder M, Gold ER, Murthy S. University technology transfer has failed to improve access to global health products during the COVID-19 pandemic. Healthc Policy [Internet]. 2022;17(4):15–25. Available from: http://dx.doi.org/10.12927/hcpol.2022.26830

Despite the significant potential to contribute to global health equity and past parliamentary recommendations to promote Canadian contributions to access to medicines, Canada has repeatedly restricted and reduced the accessibility of the outputs of its biomedical research[6]. A 2013 study analyzed six separate cases of Canadian policy disputes where improved access to medicines in developing countries has been in conflict with intellectual property rights[7]. It found that in all except one case, Canada repeatedly prioritized intellectual property rights over access, a pattern which is also evident in several domestic cases. In doing so, the life-saving potential of the products of Canadian biomedical research is left unfulfilled; Canada fails its "humanitarian duty to protect the human right to health" through this pattern of decision-making[8].

A pattern of critical decisions and consistent shortcomings in Canada's biomedical research system has emerged: universities receive significant amounts of public funding to conduct research and develop life-saving medicines, but the public does not have sufficient access to these medicines. This university research system does not always yield improvements in drug access to people in Canada and abroad. With universities at the forefront of the development and licensing of Canadian-researched medicines, it is imperative that their biomedical R&D practices actively prioritize equitable access. To maximize Canada's impact, universities must make crucial decisions in resource allocation, accessibility of their published biomedical research and its products, equitable licensing practices, and the availability of global health education offered to students on campus.

Canada has significant potential to advance global health equity, and has addressed exorbitant and inaccessible drug prices facilitated by IP policy and drug patents in the past through legislation such as the Canadian Patent Act, which saw substantial decreases in the cost of prescription drugs for Canadians[9] [10]. Equitable access to university-researched health technologies, both domestically and globally, is deeply intertwined with the commercialization of intellectual property. As such, it is imperative that government legislation consider the accessibility of the products of Canadian biomedical research and innovation in this study.

## Importance of an Access-Oriented Perspective

[6] Ourcommons.ca. "Committee Report No. 20 - HESA (42-1) - House of Commons of Canada." Accessed March 17, 2023. https://www.ourcommons.ca/DocumentViewer/en/42-1/HESA/report-20/page-21.

[7] Lexchin, Joel. "Canada and Access to Medicines in Developing Countries: Intellectual Property Rights First." *Globalization and Health* 9, no. 1 (2013): 42. https://doi.org/10.1186/1744-8603-9-42.

[8] Lexchin, Joel. "Canada and Access to Medicines in Developing Countries: Intellectual Property Rights First." *Globalization and Health* 9, no. 1 (2013): 42. https://doi.org/10.1186/1744-8603-9-42.

[9] Canada. Commission of Inquiry on the Pharmaceutical Industry, and Harry C Eastman. Report of the Commission of Inquiry on the Pharmaceutical Industry. Toronto, Ont.: The Commission, 1985. http://catalog.hathitrust.org/api/volumes/oclc/13397447.html.

[10] Gabriel, Patricia, Rebecca Goulding, Cecily Morgan-Jonker, Shannon Turvey, and Jason Nickerson. "Fostering Canadian Drug Research and Development for Neglected Tropical Diseases." *Open Medicine: A Peer-Reviewed, Independent, Open-Access Journal* 4, no. 2 (2010): e117-22.

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Existing briefs and testimonies presented to the Committee have underlined the necessity for increased funding for IP protection and education at universities as significant hubs of research and innovation. However, there currently exists a lack of access-oriented perspectives which are crucial to underline when discussing innovation and the commercialization of intellectual property, especially in the biomedical sector. This brief and the following recommendations aim to supplement existing calls to support the commercialization of IP at universities with access-oriented legislation that ensures the commercialization of the products of Canadian biomedical research improves, rather than exacerbates, existing health inequities both in Canada and across the world.

Universities Allied for Essential Medicines (UAEM) has investigated the U15 universities' biomedical R&D practices, and our findings have been compiled in the 2023 Canadian University Report Card. The following recommendations are made on the basis of our findings. Data was collected through both publicly available sources as well as self-reported data provided by the universities in the form of surveys. The data was then compiled, and the universities were scored. To read more about the Report Card, our methodology and our findings, please see https://newcanada.globalhealthgrades.org/ as well as the White Paper.

## Policy Recommendations and Key Findings

1. **Increase funding to university education specifically related to the legal aspect of IP commercialisation and biomedical R&D, with an increased focus on global health equity.**

   As previously established, Canadian universities play a crucial role in educating their students to be future global leaders as well as serving as innovation hubs. The Canadian Report Card found that only seven out of fifteen of the U15 offered courses in the last 2 academic years that address the policy and legal context of biomedical R&D, and more specifically the impact of intellectual property policies, on research priorities and global access to medical innovations[11]. By increasing funding for courses in these areas, universities will equip students with the necessary knowledge to not only develop new technologies but also how to commercialize them, which in return will drive economic outcomes. Focusing on the impact of IP commercialisation on global health equity will allow students to think critically about the impact of their work on global health outcomes and prioritize solutions which will allow for better access to medicines and healthcare outcomes in low- and middle-income countries, as defined by the World Bank. Last, biomedical R&D and IP commercialisation also raise an important number of ethical considerations, such as but not limited to access and affordability, ethical use of new technologies and licensing practices. Courses related specifically to the legal aspect of IP commercialisation will allow students to actively consider and think critically about the balance between innovation and profitability, taking a wide variety of factors into account.

[11] Crosby M, Huang C, Leloup A. 2023 Canadian Report Card: Global Equity in Biomedical Research.

2. **Create federal guidelines for universities on how to engage in non-exclusive licensing practices, as well as incentivise and increasing directed funding to support non-exclusive licenses.**

   Non-exclusive licenses allow for multiple parties to access and build upon a technology or product already created, which encourages not only innovation but also collaboration across Canadian universities as well as public-private partnerships. Furthermore, non-exclusive licensing agreements help promote global health equity by allowing for generic versions of drugs to be produced and distributed widely and in an affordable manner, thus allowing for greater access both in Canada as well as low- and middle-income countries, regardless of socioeconomic status. However, only five of the U15 universities have publicly committed to licensing their medical discoveries in ways that promote access and affordability for resource-limited populations[12]. Furthermore, twelve universities out of the U15 have not signed on to SARS-CoV-2 licensing agreements to promote intellectual property sharing with the aim of minimizing disease impact[13]. Providing federal guidelines would facilitate universities' non-exclusive licensing practices by dissolving the barrier of know-how or lack of experience, and would thus result in more non-exclusive licensing agreements being made. Moreover, promoting these equitable practices will allow Canadian universities - and Canada, as an extension - to enhance their reputation internationally and solidify their role worldwide as leaders in research and innovation and acting as role models for inclusive and equitable research practices. UAEM also found that overall, only 43.8% of total biomedical licenses were non-exclusive[14]. Increased federal funding for universities to offset the financial incentives of exclusive licenses would encourage non-exclusive licensing agreements which facilitate the production of affordable generics in lower- and middle-income countries.

3. **Increased enforcement of clinical trial transparency in accordance with the World Health Organization's Joint Statement on Public Disclosure of Results from Clinical Trials.**

   In 2020, the Canadian Institutes for Health Research signed onto the World Health Organization's Joint Statement on Public Disclosure of Results from Clinical Trials, requiring that all clinical trial results be publicly disclosed within 12 months from the last visit of the last participant[1516]. However, our data shows that only two universities out of the U15 published all of their clinical trial

[12] Crosby M, Huang C, Leloup A. 2023 Canadian Report Card: Global Equity in Biomedical Research.
[13] idem
[14] idem
[15] CIHR signs the world health organization's joint statement on public disclosure of results from clinical trials [Internet]. Cihr-irsc.gc.ca. 2020 [cited 2023 Feb 27]. Available from: https://cihr-irsc.gc.ca/e/52189.html
[16] Government of Canada, and Canadian Institutes of Health Research. "CIHR Policy Guide – Requirements for Registration and Disclosure of Results from Clinical Trials." Cihr-irsc.gc.ca, February 8, 2022. https://cihr-irsc.gc.ca/e/52820.html.

results and summary results, for clinical trials completed in the past 2 calendar years. A lack of clinical trial transparency may be attributed to intellectual property protection; there exists a conflict between the sharing of trial results and data in a system which generates value and profit through the exclusivity and protection of intellectual property[17]. Non-reporting of clinical trial results serves to limit public and expert knowledge on novel health technologies, and acts as a barrier to the dissemination of knowledge which is directly useful to patients, clinicians, and researchers in establishing a thorough background and base to understand the efficacy and limitations of medicines. Further, the unavailability of clinical trial data it hinders the ability of other researchers to develop predictive models for identifying the most appropriate treatments for patients[18]. Increased enforcement of clinical trials transparency through the timely reporting of trial results would reduce publication biases and ensure that the protection and commercialization of intellectual property do not sacrifice the accessibility of potentially life-saving treatment and efficacy information in favour of profit-driven, exclusivity-based interests.

## Summary of policy recommendations

1. Increase funding to university courses specifically related to the legal aspect of IP commercialisation and biomedical R&D, with an increased focus on global health equity.

2. Create federal guidelines for universities on how to engage in non-exclusive licensing practices, promoting Canadian universities' standing worldwide as leaders in global health equity and research, as well as increase funding to support non-exclusive licenses.

3. Increased enforcement of clinical trial transparency in accordance with the World Health Organization's Joint Statement on Public Disclosure of Results from Clinical Trials.

## About UAEM

Universities Allied for Essential Medicines (UAEM) is a student-driven nonprofit organization focused on addressing the access to medicines crisis by holding our universities accountable for their impact on the discovery and development of the world's health technologies. We are made up of student chapters all over the world and organize to fight for a right to health for every person. Read more about our work at https://uaem.org.

[17] Andanda, Pamela. "Managing Intellectual Property Rights over Clinical Trial Data to Promote Access and Benefit Sharing in Public Health." IIC; International Review of Industrial Property and Copyright Law 44, no. 2 (2013): 140–77. https://doi.org/10.1007/s40319-012-0016-z.

[18] Andanda, Pamela. "Managing Intellectual Property Rights over Clinical Trial Data to Promote Access and Benefit Sharing in Public Health." IIC; International Review of Industrial Property and Copyright Law 44, no. 2 (2013): 140–77. https://doi.org/10.1007/s40319-012-0016-z.

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## About the Authors

Justin Mendoza, MPH, is the executive director for UAEM North America. Before accepting this role in April 2023, Justin led Partners In Health's efforts on U.S. policy and advocacy strategy, where he worked on legislative policy changes like the American Rescue Plan Act and advocated for a rational COVID-19 response. Previously, Justin worked on health care priorities with Families USA and Public Citizen in Washington D.C., focused on lowering drug prices, taking on pharmaceutical patent overreach, expanding health care coverage, and lowering underlying health care costs. Justin holds an MPH in Health Policy from Yale University and a B.S. in biomedical sciences and neuroscience from Central Michigan University.

Amanda Frederiksen Leloup is a student at McGill University, pursuing a BA Joint Honours in Political Science and International Development Studies. Student-leader at UAEM, she has led the 2023 iteration of the Report Card with Celine Huang and Max Crosby. She is passionate about global health governance, believing that health and access to medicines is a human right, and that Canadian universities hold a unique role within the biomedical R&D landscape to be a leader in promoting global health equity and access.

Celine Huang is a student at McGill University, pursuing a BA&Sc. in Cognitive Science. She led the creation of the 2023 Canadian University Report Card with Amanda Frederiksen Leloup and Max Crosby, with a focus on the creation of the project's White Paper and other relevant written reports.