

**Brief Submission to Standing Committee on Health (HESA)
from Nigel Rawson, MSc, PhD**

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Standing Committee on Health (HESA)
House of Commons
131 Queen Street (Sixth Floor)
Ottawa, ON
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Subject: Submission to HESA study on PMPRB Final Guidelines

Dear Honourable Members,

As President of Eastlake Research Group, Senior Fellow with the Fraser Institute and an affiliate scholar at the Canadian Health Policy Institute, I have studied and published extensively on Canadian and comparative global pharmaceutical pricing, regulatory and reimbursement policy.

Regarding the PMPRB reforms, I developed case studies, published in a peer-reviewed journal, which show that the reforms are extremely complex. Furthermore, they will have the effect of reducing drug prices to levels that will be unsustainable for developers to commercialize medicines in Canada.

My research has demonstrated that drug prices will have to be reduced between 45-75%, which will lead either to delays in new drugs being launched in Canada or not being brought here at all. Severe price reductions will drastically reduce Canada's attractiveness for drug developers as a country in which to do business.

Drastic regulatory price reductions have direct consequences on research and development, clinical trials, and access to medicines in Canada. The impacts are already being felt.

The average percentage of new medicines approved in Canada either before approval in the U.S. or within a year after U.S. approval between 2013 and 2015 was 55%. However, the figure was 45% in 2018 and only 15.6% in 2019. It is important to note that these data are pre-COVID.

Clinical trials will also be affected by the reforms. New trials registered with Health Canada from November 1, 2019, through to the end of February 2020 fell by almost 60% compared with the average of those registered in the same period in the preceding four years. Comparable data for the United States show no similar decrease.

In addition, it is crucial to note that Health Canada has recently made an exception for vaccines and therapeutics for COVID-19, exempting them from having to follow the PMPRB regulations. This is proof that the regulations are an impediment to bringing new medicines to Canada.

I have included an appendix to this submission with citations to articles that I have authored or co-authored on the PMPRB reforms for the committee's consideration.

Finally, I urge the members of the Health Committee to call on the Government of Canada to review the proposed regulations using a case study approach that reflects the realities which medicine and vaccine developers face in Canada and around the world. The Government's objective should shift from one that is almost exclusively focused on price controls and affordability to goals that reflect the need for patient and health system access to new therapeutics that save and improve lives.

I wish you all the best in your deliberations.

Yours truly,

A handwritten signature in black ink, appearing to read 'Nigel Rawson', followed by a period.

Nigel Rawson, MSc, PhD

Appendix – Publications Related to PMPRB Reforms

- Rawson NSB. Leading causes of mortality and prescription drug coverage in Canada and New Zealand. *Frontiers in Public Health* 2020; 8: 544835.
- Rawson NSB. Clinical trials in Canada decrease: a sign of uncertainty regarding changes to the PMPRB? *Canadian Health Policy*. Toronto: Canadian Health Policy Institute, April 2, 2020.
- Rawson NSB. Fewer new drug approvals in Canada: early indications of unintended consequences from new patented medicines regulations. *Canadian Health Policy*. Toronto: Canadian Health Policy Institute, March 23, 2020.
- Rawson NSB, Lawrence D. New patented medicine regulations in Canada: updated case study of a manufacturer's decision-making about a regulatory submission for a rare disorder treatment. *Canadian Health Policy*. Toronto: Canadian Health Policy Institute, January 20, 2020.
- Rawson NSB, Adams J. Access to new medicines: what Ottawa should learn from COVID-19. Macdonald-Laurier Institute for Public Policy, June 2020.
- Rawson NSB. New patented medicine regulations in Canada: case study of a manufacturer's decision-making about regulatory submission for a rare disorder treatment. *Canadian Health Policy*. Toronto: Canadian Health Policy Institute, October 2018.
- Rawson NSB, Adams J. Exempting COVID medicines from new price controls: Ottawa hypocrisy. Ottawa: *National Newswatch*, October 14, 2020.
- Rawson NSB, Adams J. Under the hood of drug price control. Toronto: *Financial Post*, July 24, 2020.
- Rawson NSB. The Patented Medicine Prices Review Board is selling Canadians a lemon. Ottawa: Macdonald-Laurier Institute for Public Policy, July 8, 2020.
- Rawson NSB. Government refuses to address real cause of missing cystic fibrosis treatment in Canada. Ottawa: *National Newswatch*, June 1, 2020.
- Rawson NSB, Koester O. Don't let price controls delay access to vaccine. Toronto: *Financial Post*, May 12, 2020.
- Rawson NSB, Adams J. Counterpoint: low prices won't keep new medicines out of Canada. Toronto: *Financial Post*, March 19, 2020.

Rawson NSB, Adams J. Price controls imposed by short-sighted politicians keep new life-saving drugs out. Toronto: *Financial Post*, March 5, 2020.

Skinner B, Rawson NSB. Extreme regulations to lower drug prices mean Canada will get fewer new drugs. Toronto: *Financial Post*, February 7, 2020.

Rawson NSB, Adams J. New rules will keep the best medications from desperate Canadians. Toronto: *Financial Post*, September 12, 2019.

Rawson NSB. Ottawa's move to cut drug prices may lead to fewer new launches, less R and D. Toronto: *Globe and Mail*, August 13, 2019.

Rawson NSB. Proposed new drug regulations will hurt all Canadians – and Ottawa has been warned. Toronto: *Financial Post*, August 13, 2019.

Rawson NSB. Ottawa blocking access to innovative drugs, writes pharmaceutical policy researcher Nigel Rawson. *Hamilton Spectator* January 19, 2018.

Rawson NSB, Barua B. Ottawa's proposed changes to review board will reduce access to prescription drugs. *Winnipeg Free Press* July 6, 2017.