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To the Standing Committee on Health (HESA), House of Commons, Canada:

I am pleased to submit for your consideration comments on the Study on Federally Funded Health Research (M-132). My name is Suerie Moon, I am the Director of Research at the Global Health Centre of the Graduate Institute of International and Development Studies, Geneva and Adjunct Lecturer on Global Health at the Harvard T.H. Chan School of Public Health, Boston. I have conducted policy-relevant research on the interlinked issues of innovation and access to medicines for the past twenty years. I have published widely on the topic, serve on a number of expert and advisory committees, including the World Health Organization (WHO) Advisory Group on Fair Pricing of Medicines, and speak regularly to media and conferences on the subject.

First, I thank and congratulate the Standing Committee on Health for dedicating attention to the important role of public funding in advancing medical innovation and ensuring that the public receives a fair and adequate return on that investment. It is well-established that public funding plays a crucial role in biomedical advances, and that this role is even more signficant for medicines that address unmet needs and represent important therapeutic advance.[1] Publicly-funded health R&D not only plays a role in financing basic research in academic centers, which is widely appreciated; it also plays a major role in funding R&D in areas where the current market-based system fails to deliver adequate investment, such as for neglected diseases, products for potential epidemics of emerging infectious disease (e.g. Ebola, MERS, Zika), and antibiotics.[2] This aspect of public funding is less well-understood, but highlights the fact that R&D is fundamentally a public/private enterprise that requires not only contributions from industry but also those of the public sector and public purse.[3]

Recently there has been increasing concern worldwide regarding the rising prices of new medicines, the resulting limits on population access to such medicines, and the strain on health systems. These concerns have been expressed at the highest political levels, not only in Canada, but across the OECD countries and low- and middle-income countries. As a result, there is increasing scrutiny of whether adequate conditions are placed on public R&D funding to ensure that medicines and other health technologies are affordable to the very publics who have financed their development. Recognition has grown that private capture of the rents of public investment has become a major problem. The Ebola rVSV vaccine that originated in

[1] Sampat BN, Lichtenberg FR. What are the respective roles of the public and private sectors in pharmaceutical innovation?. Health Affairs. 2011 Feb 1;30(2):332-9.
[2] Chapman N, Doubell A, Oversteegen L, Chowdhary V, Rugarabamu G, Zanetti R, Ong M, Borri J. Neglected disease research and development: Reflecting on a decade of global investment. Policy Cures Research. 2017.
[3] Moon S. Powerful ideas for global access to medicines. New England Journal of Medicine. 2017 Feb 9;376(6):505-7.

Canadian public labs as a result of public investment of Canadian dollars over a decade ago has resulted in a product that today promises to help control an outbreak of Ebola in the Democratic Republic of Congo – but may not be affordable or available to Canadians or others who may need the vaccine in case international transmission occurs again. A forthcoming study shows that the vast majority of R&D funding to develop this Ebola vaccine – now manufactured by Merck – came from public funds from Canada and Norway, together with philanthropic funds from Medecins Sans Frontieres and others.

A key question is whether the government can put conditionalities on public funds for health research to require affordable pricing of health technologies that may result. There is a fear that onerous conditionalities will be unattractive to private investors. Experience from the global health arena, where alternate approaches to R&D have been implemented for the past two decades, demonstrates that it is indeed feasible to require affordable pricing as a condition of receiving public or philanthropic funds, and that many companies have agreed to affordable pricing for various reasons. See, for example, the experience of developing an affordable vaccine against meningitis.[4] Some measures to do so include :

- Including affordability targets in Target Product Profiles.
- During R&D processes, ensure the systematic inclusion of a commitment to affordable pricing of end-products in every technology development grant, contract, or other agreement.
- Seek to minimize manufacturing costs of the end product, without compromising on safety, efficacy or quality, in order to facilitate maximum affordability of the end product.
- When the products have been developed, seek the “lowest sustainable[5] prices” in as many countries as possible, with an emphasis on low- and middle-income countries. “Lowest sustainable prices” are defined as prices that will cover manufacturing costs, at an acceptable level of quality, provide producers with a reasonable profit margin, and ensure adequate and secure supply.[6] Prices in high-income countries may reasonably be higher than in developing countries, but should still fall below an affordability threshhold.
- In countries where the lowest-sustainable price is not feasible, require sellers to commit to fair, affordable, transparent pricing.
- Prices in various markets should reflect the relative contributions of different actors to product development. Grantees can be required to provide transparent information regarding the contributions of financing, expertise, and other in-kind resources, and at which stage in the R&D

[4] LaForce FM, Djingarey M, Viviani S, Preziosi MP. Lessons from the Meningitis Vaccine Project. Viral immunology. 2018 Mar 1;31(2):109-13.

[5] In some cases the lowest sustainable price (e.g. marginal cost of production) will still be unaffordable for certain populations. In such cases, other interventions will be required to achieve affordability.

[6] Tools to achieve affordability include competitive multi-source supply, or single-source supply with cost-plus pricing, cost audits, cost-effectiveness analyses and price ceilings. A number of policy tools can be used to facilitate competitive multi-source supply, including de-linkage, non-exclusive compulsory or voluntary licensing, patentability criteria, competition law, technology transfer, ease of registration.

process. While agreements will need to be negotiated on a case-by-case basis, in general pricing should reflect the degree of risk and costs borne by public-interest and private-interest organizations.

- When producers are unable to meet pricing or supply commitments, government should retain the right to require the transfer of technology and all relevant intellectual property and other legal rights to enable a third party to supply the product.
- Grantees should commit to ensure public disclosure of the source and level of all public funds received for R&D of the product.
- Grantee should commit to pursue strategies that de-link R&D costs from end-product prices.
- Grantees should commit to approach the management of knowledge, including potential and existing intellectual property rights, in a manner that will maximize affordability,[7] innovation, availability and access to knowledge.

These policies and provisions are an important step towards ensuring that medicines and other health technologies are available to all, and that public funds generate a fair return on public investment.

Please do not hesitate to contact me if I can provide any further information.

Sincerely,

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[7] Tools to achieve these ends include: not seeking IPRs, transparent disclosure of IP ownership and rights, non-enforcement of IPRs, non-exclusive licensing for competitive production, licensing to facilitate follow-on or open innovation, waiving data exclusivity rights, and defensive patenting to maximize access to the relevant knowledge. and other terms and conditions that contribute to affordability, innovation and availability of medical technologies