Minister of Health | Ministre de la Santé

Ottawa, Canada K1A 0K9

Bill Casey, M.P.
Chair
Standing Committee on Health
The House of Commons
Ottawa, Ontario
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Dear Mr. Casey:

Pursuant to Standing Order 109 of the House of Commons, on behalf of the Government of Canada, I am pleased to respond to the twentieth Report of the Standing Committee on Health entitled *Towards Open Science: Promoting Innovation in Pharmaceutical Research and Development and Access to Affordable Medications Both in Canada and Abroad,* tabled in the House of Commons on November 26, 2018.

First, I would like to thank Mr. Saini for bringing this important issue to the Committee's attention. I would also like to thank the Committee for its efforts in preparing the report and acknowledge the recommendations provided. The Government of Canada agrees with the spirit of the Committee's recommendations on the need to foster innovative, collaborative and accessible health research that produces effective outcomes for Canadians.

The Government, in response to the Fundamental Science Review commissioned by the Honourable Kirsty Duncan, Minister of Science and Sport, has moved forward with a series of initiatives aimed at ensuring that Canadian researchers have the tools, training and support needed to excel globally and produce world-leading research that improves the lives of Canadians. I wish to briefly highlight some initiatives the Government has undertaken to modernize the science funding ecosystem in Canada before addressing the Committee's recommendations relating to the themes of open science, research, and access to medication.

In Budget 2018, the Government proposed a historic investment of nearly $4 billion for Canadian science to ensure that Canada's current and future scientists can thrive. This included a proposed investment of $354.7 million over five years, starting in 2018-19, to the Canadian Institutes of Health Research (CIHR) to increase support for fundamental health research to expand the base of research evidence available to address critical health challenges.

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In 2017, the Government of Canada established the Canada Research Coordinating Committee (CRCC) to achieve greater harmonization, integration and coordination of research-related programs and policies across the federal granting councils (the Canadian Institutes of Health Research (CIHR), Natural Sciences and Engineering Research Council (NSERC), and the Social Sciences and Humanities Research Council (SSHRC)) and the Canada Foundation for Innovation (CFI), which provides research infrastructure support. Budget 2018 proposed $275 million over five years, and $65 million per year ongoing, for a new Tri-Agency research fund aimed at supporting research that is international, interdisciplinary, fast-breaking and higher-risk. This fund, the New Frontiers in Research Fund (NFRF), represents a fundamental shift in how Canada invests in research and aims to accelerate the pace of scientific discovery to improve our economy and the quality of life of Canadians.

These investments recognize the transformational potential of research and signal the Government's commitment to strengthening the scientific enterprise in Canada while promoting the fair and transparent allocation of public research funds.

***Promoting Open Science in Canada and Abroad***

As the Committee's report indicates, momentum for open science has been growing in recent years as numerous funding agencies and institutions worldwide implement open access policies. The Government recognizes that open access to research results helps to advance knowledge, avoid research duplication and encourage reuse, and ultimately can contribute to maximizing research benefits to Canadians. In this spirit, our Government has moved forward with developing a series of policies and action plans aimed at enhancing the accessibility and usability of federally funded research. One such initiative is the recently released fourth iteration of Canada's Action Plan on Open Government (2018-2020), which includes a commitment to support and promote open science though the following:

- developing a Canada Open Science Roadmap to provide a plan for greater openness in federal science and research activities;
- providing a platform for Canadians to find and access open access publications from federally funded scientists;
- raising public awareness of federal scientists' work and of open science;
- promoting open science and soliciting feedback on stakeholder needs, including hosting open science engagement sessions with stakeholders across Canada
- developing measurement tools and indicators to monitor progress in implementing open science and the benefits it can provide.

This commitment is building on previous federal initiatives related to open access to the results of federally-funded research.

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The Government acknowledges that research data collected with the use of public funds should, to the fullest extent possible, be available in the public domain for reuse by others. As such, the three federal research granting agencies (CIHR, NSERC and SSHRC) have several policies in place to promote the accessibility of research data and results stemming from public funds. This includes the Tri-Agency Open Access Policy on Publications, whereby researchers must ensure that peer-reviewed journal publications arising from CIHR, NSERC or SSHRC supported research are freely available within 12 months of publication by depositing manuscripts in an institutional or disciplinary repository and/or publishing in an open access journal.

The Government also recognizes the importance of sound data management and stewardship practices as in integral component of advancing open science and supporting innovation in Canada. In this vein, the federal granting agencies released the Tri-Agency Research Data Management Policy for public consultation in the summer of 2018. The policy would require federally funded researchers to deposit into a recognized digital repository all digital research data, metadata and code that directly support the research conclusions in journal publications, pre-prints, and other research outputs that arise from agency-supported research. Consultations on the policy closed on August 31, 2018 and the final Tri-Agency policy is forthcoming.

The Government is also committed to supporting a modern and robust Intellectual Property (IP) system in Canada which provides incentives for research and development. The federal granting agencies, in accordance with the Tri-Council Policy on Intellectual Property, do not retain, or claim any ownership of, or exploitation or proprietary rights to, intellectual property, copyright or inventions developed/resulting from research supported with agency grant funds nor does it pass judgment on the eventual commercial success of the research. IP rights stemming from federally funded research are administered in accordance with the practices and policies of the host institutions, namely universities, with global access licensing to IP remaining at the discretion of the owner. In 2018, our Government launched the Intellectual Property Strategy with an investment of $85.3 million over five years to help Canadian businesses and innovators understand, protect and access IP, and to help our innovators compete globally. This strategy seeks to make Canada a leader in generating and strategically leveraging IP investments to benefit Canadian innovation, including those related to the development of novel therapeutics. One of the key pillars of the IP strategy focuses on education, outreach and advice. As part of this pillar, the Canadian Intellectual Property Office (CIPO) will continue to build on current learning tools and resources and will develop new educational resources to better equip innovators, researchers and businesses with the knowledge they need to navigate the IP system.

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Finally, our Government recognizes the importance of integrating sex and gender into health research when appropriate as expressed in the Health Portfolio Sex and Gender-Based Analysis Policy, of which CIHR is a signatory. Sex (biological attributes) and gender (socio-cultural factors) influence the risk of developing certain diseases, how well individual's respond to medical treatments, including pharmaceuticals, and how often individual's seek health care. As such, CIHR has a Sex and Gender-Based Analysis (SGBA) in Research Action Plan in place to ensure that health research funded through CIHR leads to sound science and reliable evidence that effectively addresses biological (sex) and sociocultural (gender and other identity factors) differences between diverse groups of people. Accounting for sex and gender in health research has the potential to make health research more rigorous, more reproducible and more applicable to everyone thereby strengthening Canada's contributions to open science.

***Supporting Health Innovation in Canada***

Through CIHR, the Government of Canada funds research across the health spectrum, supporting new scientific knowledge and enabling its translation into real world solutions. As the Committee's report acknowledges, this includes fundamental research, and clinical research. It is important to note that CIHR also supports health services research to improve the efficiency and effectiveness of health professionals and the health system through changes to practice and policy. In addition, CIHR supports population and public health research to improve the health of the Canadians through a better understanding of the ways in which social, cultural, and environmental factors influence health. CIHR supports the translation of federally-funded research evidence into effective outcomes for Canadians through a number of its strategic initiatives.

One of CIHR's major initiatives is Canada's Strategy for Patient-Oriented Research (SPOR), which is a unique collaboration of federal, provincial and territorial partners, all dedicated to the translation of research knowledge into care. As part of SPOR, CIHR is investing $11.7 million a year in the innovative Clinical Trials (iCT) Initiative that focuses on the development and implementation of innovative methods in clinical research. The iCT Initiative aims to provide a stimulus for researchers to adopt new methodologies to conduct clinical trials. The direct outcome of these new methods is an improved effectiveness of clinical trials while keeping the same high safety and effectiveness standards as traditional trials. Specifically for drug trials, this approach may potentially contribute to lowering the cost of drug development, ensuring that new affordable and effective drugs are available for Canadians.

Further, CIHR is investing $17.5 million a year in SPOR Networks, which are national collaborative research networks involving researchers, patients, policy makers, academic health centres, health charities, and other stakeholders. SPOR Networks

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address research priorities identified by various stakeholders, including patients, and accelerate the translation of research findings into patient care and health care policy, including priorities related to the development of new therapies and improved access to medications. For example, clinical trials are a component of many of the Networks' research programs with work ongoing to develop new therapies for cerebral palsy and Type 1 diabetes along with work to develop combination analgesics to enhance clinical management of pain.

Through international collaborations, CIHR supports the translation of research evidence into health innovations that have the potential to make a real impact on the health of Canadians, particularly those living with rare diseases. For example, CIHR is a founding member of the International Rare Diseases Research Consortium (IRDiRC), which aimed to deliver 200 new therapies for rare diseases by 2020. As of 2016, IRDiRC has bi-passed this goal and a new goal of delivering 1000 new therapies has been set for the next 10 years. Canada is also engaged in E-Rare, the European Union's main instrument for funding research in areas related to rare diseases. This initiative enables scientists in different countries to collaborate on a common interdisciplinary research project, with a clear translational approach.

In addition, in 2009, CIHR and Health Canada created the Drug Safety and Effectiveness Network (DSEN) to systematically conduct "real world" drug safety and effectiveness research required by Canadian decision-makers. DSEN is a national network of over 200 researchers and receives $10 million per year in ongoing funding from the Government to support its work in answering priority research questions. For example, research provided by DSEN informed the Public Health Agency of Canada's (PHAC) National Advisory Committee on Immunization guidance on herpes zoster vaccines. To further facilitate the knowledge translation process, DSEN developed a collaborative agreement with the Canadian Agency for Drugs and Technologies in Health (CADTH), an independent organization, to disseminate DSEN study results to provincial and territorial health authorities. DSEN is yet another example of a Government funded initiative that creates the capacity to respond in a timely manner to the drug safety and effectiveness queries of decision makers, and ensures that the most effective drugs are accessible to Canadians.

CIHR further supports health innovation through knowledge translation activities such as the Best Brain Exchanges (BBE) program which is designed to deliver high-quality, timely, and accessible research evidence that responds to health system policy issues and gaps in knowledge, to inform policy development, planning and program implementation. As an example, in 2016, CIHR, in collaboration with the Ontario Ministry of Health and Long-Term Care, hosted a BBE that explored leading research and implementation evidence to support the collaborative efforts of the Federal, Provincial and Territorial governments in relation to the accessibility, appropriateness, and affordability of prescription drugs.

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Finally, since 1989 CIHR, in collaboration with NSERC and SSHRC, has supported the Networks of Centres of Excellence (NCE) program that mobilizes Canada's best research, development and entrepreneurial expertise and focuses it on specific issues and strategic areas, including several in the area of pharmaceutical development. For example, through the NCE program the Government of Canada supports Accel-RX Health Sciences Accelerator (Accel-RX) which leverages the expertise and infrastructure of seven health-related Centres of Excellence for Commercialization and Research (CECRs), including the Centre for Drug Research and Development (CDRD), to aid in the further screening and evaluation of technologies with the highest technical and commercial potential. One such example is the investment of Accel-RX, in partnership with MaRS Innovation and CDRD, in Zucara Therapeutics to develop an antibody treatment for insulin dependent diabetics to prevent hypoglycemia. This investment will allow Zucara to select a lead candidate and generate in vivo validating data to support a clinical trial application.

The Government recognizes that NCEs have made significant contributions to the research and innovation landscape in Canada while also acknowledging that there is a need to streamline and modernize programs in support of research in Canada. As reflected in its historic investments in research in Budget 2018, our Government remains committed to continuing to support Canadian researchers and collaborative networks of researchers with funding from the NCE program gradually being transferred to the New Frontiers in Research Fund over the next several years.

***Improving the Accessibility and Affordability of Medication***

The Government recognizes that access to safe, effective and affordable medicines is important to Canada's ongoing efforts to promote health both on a national as well as a global level. Budget 2017 outlined investments of $140.3 million over five years, with $18.2 million ongoing annually thereafter, for Health Canada, the Patented Medicine Prices Review Board (PMPRB) and the Canadian Agency for Drugs and Technologies in Health (CADTH) to improve accessibility and affordability as well as support appropriate prescribing and use of prescription drugs. Through these investments, Health Canada is working to modernize its regulatory system in order to provide agile pathways to bring needed drugs to Canadians. Further, Budget 2017 investments enabled the PMPRB to propose regulations and to launch consultations on the proposed regulations that may further reduce the cost of prescription drugs.

In addition, the Government has also been working collaboratively with provinces and territories to enhance the affordability, accessibility, and appropriate use of prescription drugs in Canada. In August 2017, federal, provincial and territorial (FPT) Ministers of Health agreed to a Common Statement of Principles on Shared Health Priorities. This

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statement sets out joint priorities for action and a commitment to measure progress and report to Canadians. In addition, in March 2017, the Government of Canada and the Government of Quebec agreed to an asymmetrical arrangement distinct from this Statement of Principles.

In Budget 2018, our Government announced the creation of an Advisory Council on the Implementation of National Pharmacare (the Council). The Council is undertaking consultations with Canadians and provincial, territorial and Indigenous leaders, as well as experts, stakeholders and patients along with conducting a fiscal, economic and social assessment of domestic and international pharmacare models. The Council is aiming to provide independent advice to our Government by spring 2019 on how best to implement national pharmacare in a way that is affordable for Canadians and their families, governments and employers. Guided by the consultations and interim report of the Council, Budget 2019 announced the Government's intention to move forward on three foundational elements of national pharmacare: the creation of the Canadian Drug Agency; the development of a national formulary; and, the creation of a national strategy for high-cost drugs for rare diseases.

On the global level, the Government actively participates in several multilateral fora advocating for access to affordable medicines at the research and development (R&D) stage, identifying and investigating ways to address barriers to access, and promoting innovative use of existing mechanisms to improve access. Canada also actively engages in discussions on access to medicines at the World Trade Organization (WTO) Council for the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and the World Intellectual Property Organization (WIPO). For instance, at its most recent session, the WIPO Standing Committee on the Law of Patents adopted a proposal from Canada and a number of other countries to conduct a review of the literature on access to medicines and health technologies, with a view to enhancing countries' understanding of these important issues. Recently, the Government supported the inclusion of R&D components in the World Health Organization's Roadmap for access to medicines, vaccines and health products, 2019-2023, which is currently under development.

The Government considers access to medicines to be a key priority in our ongoing efforts to promote global health and prosperity. As such, the Government's international development priorities and significant investments in strengthening health systems and the health and rights of women and children are contributing to improved access. For instance, Global Affairs Canada collaborates with CIHR and the International Development Research Centre (IDRC) to co-fund a $36 million, seven year, implementation research program called "Innovating for Maternal and Child Health in Africa (IMCHA)" to support projects that investigate and look for solutions to bottlenecks in primary health care for mothers and children in Sub-Saharan Africa. Further, Canada

was the founding donor of the Stop TB Partnership's Global Drug Facility and is a global leader in supporting partnerships such as the Global Fund to Fight AIDS, Tuberculosis and Malaria; and Gavi, the Vaccine Alliance, which strengthen health systems and provide targeted programming to increase access to medicines and vaccines.

As evidenced through the aforementioned policies, action plans, partnerships and strategic research initiatives the Government is committed to supporting innovative, collaborative and accessible health research that makes good use of federal funds while producing improved health services and products and more effective health outcomes for Canadians.

Yours sincerely,

The Honourable Ginette Petitpas Taylor, P.C., M.P.
Minister of Health