Johnson & Johnson
FAMILY OF COMPANIES IN CANADA

August 3, 2018

Hon. Wayne Easter
Chair, Standing Committee on Finance
House of Commons
Ottawa, ON
K1A 0A6

Via Finance Committee Website

Re: Written Submission for the Pre-Budget Consultations in Advance of the 2019 Budget

Dear Mr. Easter,

The Johnson & Johnson Family of Companies in Canada ("Johnson & Johnson") is a leader in Canada's health sector, researching, developing and manufacturing consumer health and personal care products, breakthrough pharmaceutical medicines and medical devices. Johnson & Johnson consists of six businesses employing more than 2,100 employees across Canada.

Our vision is to enrich the health and wellness of every Canadian every day. Johnson & Johnson is committed to leading our industry's support of sound public policies which enable increased competitiveness, advance innovation to improve the health of Canadians and make life-changing and sustainable differences in human health. Collaboration between the federal government and key stakeholders, such as industry, is critical to achieving this goal.

On behalf of Johnson & Johnson, we appreciate the opportunity to share our views with you on steps the federal government can take to support the innovative Canadian life sciences sector to grow the economy in the face of a changing economic landscape in Budget 2019 Should you have any questions regarding Johnson & Johnson's submission, please do not hesitate to contact me directly at 416-301-7352 or at lbabiak@its.jnj.com.

Sincerely,

Dr. Lesia M. Babiak, BscPharm, PharmD, MBA
Executive Director, Worldwide Government Affairs & Policy (Canada)
Chair, Government Affairs Council

Johnson & Johnson
FAMILY OF COMPANIES IN CANADA

Recommendations from the Johnson & Johnson Family of Companies in Canada:

Recommendation 1: That the federal government reassess the proposed regulatory revisions to the Patented Medicines Regulations to ensure competitiveness within the Canadian life sciences sector is enhanced, not inhibited.

Recommendation 2: That the federal government leverage regulatory review of the health/bio-sciences sector to align and harmonize regulatory requirements for health products with leading jurisdictions, while reducing the cumulative impact of regulatory changes.

Recommendation 3: That the federal government conclude negotiations towards a modern North American Free Trade Agreement (NAFTA) with the United States and Mexico and reverse retaliatory measures implemented in July 2018.

Recommendation 4: That the federal government ensure that any plans to implement national pharmacare are focused firstly on ensuring improved access to medicines for Canadians.

Recommendation 1: That the federal government reassess the proposed regulatory revisions to the Patented Medicines Regulations to ensure competitiveness within the Canadian life sciences sector is enhanced, not inhibited

Johnson & Johnson supports the federal government's efforts to make pharmaceuticals more affordable for Canadians. There are ways to reduce drug prices that preserve Canada's status as a desirable place for research and innovation to occur.

However, the federal government has proposed significant regulatory reform to the Patented Medicine Prices Review Board (PMPRB), which would fundamentally change the way that the prices of patented medicines are regulated in Canada. At a high level, this regulatory proposal would see prices of patented medicines reduced by 25-30%. The Federal Government estimates that industry will lose $8.6 billion in revenues over 10 years, but the industry analysis indicates a far greater impact. In addition, the proposed regulations have a far broader impact than the stated intention to reduce prices. They will not result in their stated goal of improved access and affordability for public drug plans and the uninsured or under-insured. It is a false assumption that the industry can absorb this type of reduction in revenues, maintain our current level of investment and jobs in Canada, and have no impact on access to new medicines.

This concern does not only impact industry, but also Canada's competitiveness and trade relationships. Earlier this year, the United States Trade Representative's 2018 Special 301 Report noted specific concern with the proposed PMPRB changes:

> "If implemented, the changes would significantly undermine the marketplace for innovative pharmaceutical products, delay or prevent the introduction of new medicines in Canada and reduce investments in Canada's life sciences sector."

The innovative pharmaceutical industry is willing to work with government to achieve their objectives – not only on price reduction, but on fostering innovation – through collaboration and partnership that preserves our ability to improve access to new drugs for Canadians and maintain our jobs and investment in Canada. Our industry has tabled a proposal that provides an alternative policy approach that would result in savings for taxpayers while allowing our industry to continue to invest in Canada.

The federal government, in receipt of this proposal, is still considering how to amend the Regulations. To assist in decision-making, Dr. David Dodge is conducting an independent third-party review of the Regulations and the associated cost-benefit analysis.

Concerningly, the PMPRB is carrying forward with consultations on proposed Guideline reform, despite the regulatory package remaining under consideration by government.

Reforming pricing regulation significantly impacts the competitiveness of Canada's innovative pharmaceutical sector. Federal leadership is required to ensure that PMPRB mandate reform process provides adequate opportunity for the regulatory process to conclude before proceeding with Guideline consultations and that Dr. Dodge's independent third-party review is provided with ample time and opportunity to fulsomely review and make recommendations on the regulatory proposal. It is critical that this process be allowed to conclude prior to the PMPRB undertaking consultations on Guideline reform so that the outcome of the process is not prejudged and the third-party review is not undermined.

Therefore, we request that the government ensure that the regulatory consultation process for amendments to the Patented Medicine Regulations, including the independent third-party review, be fully concluded prior to consulting on revisions to the Patented Medicine Prices Review Board Guidelines.

Recommendation 2: That the federal government leverage regulatory review of the health/bio-sciences sector to align and harmonize regulatory requirements for health products with leading jurisdictions, while reducing the cumulative impact of regulatory changes.

Johnson & Johnson applauds the federal government's commitment in Budget 2018 to modernize Canada's regulatory frameworks. Reflecting the advice of the Advisory Council on Economic Growth, regulatory review of the health/bio-sciences sector is vitally important to ensuring Canada remains competitive in a global marketplace.

The most significant outcome of the Regulatory Review and Modernization process is to align and harmonize regulatory requirements with leading jurisdictions where possible. Building on regulatory cooperation efforts with the United States through the Regulatory Cooperation Council and emerging under CETA with the Canada-EU Regulatory Cooperation Forum, Canada has an opportunity to reduce barriers to innovative products by reducing or eliminating regulatory barriers to the Canadian market.

Clinical data transparency is an area of specific concern to Johnson & Johnson that is well-positioned for regulatory harmonization. Johnson & Johnson urges Health Canada to work proactively with other major regulators to harmonize the approach to clinical data transparency to the fullest extent, to avoid an unsustainable proliferation of incrementally different approaches requiring regulatory compliance. It is recommended that opportunities to progress discussions on achieving international harmonization through forums such as the International Pharmaceutical Regulators Program (IPRP) or International Medical Device Regulators Forum and ICH should be pursued.

Regulatory review also provides an opportunity to consider the cumulative impact of multiple ongoing and future regulatory changes facing our sector. From amendments on plain language labelling to recently proposed changes to the *Patented Medicines Regulations,* and proposed cost recovery fee increases, there are numerous initiatives underway both federal and provincial, which are challenging the business and regulatory environment for drugs and medical devices in Canada. Health Canada's Regulatory Review of Drugs and Devices includes a suite of 15 regulatory reforms which will transform Health Canada's regulatory approach.

When taken cumulatively, there is significant concern that the accumulated proposed regulatory changes for drugs and devices and the changes in the business environment will significantly increase costs and regulatory burden for manufacturers, and will lead to unintended and negative consequences for Canadians and the health care system. It is imperative that regulatory alignment and harmonization is sought to reduce unique Canadian regulatory requirements that are resource intensive and may discourage companies from filing drug and device applications in Canada.

Recommendation 3: That the federal government conclude negotiations towards a modern North American Free Trade Agreement (NAFTA) with the United States and Mexico and reverse retaliatory measures implemented in July 2018.

A modern North American Free Trade Agreement (NAFTA) is critical to ensuring a stable, predictable, and competitive business environment for the economy of today and the future. This is key to ensuring that Canada maintains its position as a G7-leading economy and creates the conditions for high-potential sectors, like Canada's life sciences sector to grow and flourish.

Johnson & Johnson has been supportive of the efforts to modernize NAFTA and we see tremendous benefit to all three member countries to update and improve the agreement to reflect the realities of business in the 21st century. The Johnson & Johnson Family of Companies has worked closely with governments in Canada, the U.S. and Mexico to support and advance negotiations towards a modernized NAFTA.

It is unfortunate that Canada felt compelled to enact retaliatory measures this past July in response to unprovoked and punitive tariffs from the U.S. It is our sincere hope that this dispute is only temporary in nature, as Canada's proposed countermeasures have a direct impact on our Family of Companies and impact the Canadians who rely on our products for health and wellness.

Concluding a sustainable, modernized NAFTA agreement will ensure that Canada's economy remains competitive, driving investment and bringing innovation to Canada. Successful conclusion of a modernized NAFTA would also require that any retaliatory measures be reversed, reducing costs to Johnson & Johnson and Canadian consumers.

Recommendation 4: That the federal government ensure that any plans to implement national pharmacare are focused firstly on ensuring improved access to medicines for Canadians.

Johnson & Johnson fully supports the concept of ensuring that every Canadian has access to the medicines they need, without cost being a barrier and we applaud the focus on examining ways to improve the pharmaceutical reimbursement system in Canada, through the work of the Advisory Council on Implementation of National Pharmacare, chaired by Dr. Eric Hoskins. We are concerned however, that much of the conversation regarding national pharmacare has focused on saving money, which while a goal we should all strive to achieve, it should not be the primary goal of this policy initiative.

Johnson & Johnson is fully committed to engaging with payers across the country to help develop a national plan that will provide new coverage to those who have no insurance for medicines, as well as those who cannot afford the deductibles or co-pays implemented by public and private plans. We caution the government to be thorough in the consultations on this topic, particularly regarding the assumption that a single-payer system will save money overall, while still providing the level of access to innovative medicines Canadians require for optimal health.

If national pharmacare is included in Budget 2019, a full costing to the Canadian taxpayers needs to be clearly articulated, as well as a clear description of the type and level of access to innovative medicines this expense will enable.