Johnson & Johnson
FAMILY OF COMPANIES IN CANADA

February 18, 2016

Hon. Wayne Easter, P.C., M.P.
Chair, Standing Committee on Finance
House of Commons
Ottawa, Ontario
K1A 0A6

By email: finapbc-cpb@parl.gc.ca

Re: Johnson & Johnson Family of Companies in Canada Recommendations for the 2016 Federal Budget

Dear Mr. Easter,

On behalf of the Johnson & Johnson Family of Companies in Canada (J&J), I would like to thank you for the opportunity to provide input into the federal government's pre-budget consultations for the 2016 federal budget.

J&J is a leader in Canada's health care sector, active in researching, developing and manufacturing consumer health care products, pharmaceuticals, medical devices and diagnostics. Our five businesses in Canada employ more than 2,500 Canadians and are committed to improving the health and well-being of Canadians every day.

Our vision is to enrich the health and wellness of every Canadian every day. J&J is committed to leading our industry's support of sound public policies which support increased competitiveness in North America, improved health and safety of Canadians and achieve a sustainable health care system. Collaboration between the federal government and key stakeholders, such as industry, are critical to developing and implementing strong public policies.

Our submission focuses on four policies which we feel will improve health for all Canadians and enhance the competitiveness of Canada's innovative health care sector: providing Canadians with tax relief on over-the-counter medicines; support for consumer education programs to ensure the safe use

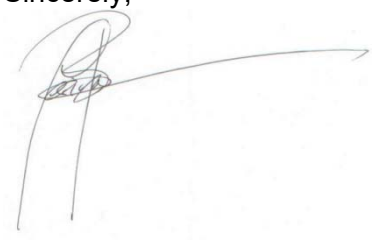
…/2

Johnson & Johnson
FAMILY OF COMPANIES IN CANADA

of medicines; international trade and intellectual property protection for pharmaceuticals; and capturing the full value of medicines to the health of Canadians.

Thank you for the opportunity to provide you with our views on Budget 2016. Should you have any questions regarding J&J'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

FAMILY OF COMPANIES IN CANADA

2016 Pre-Budget Consultation Submission

On behalf of the Johnson & Johnson Family of Companies in Canada (J&J), we are pleased to submit the following priorities to the Minister of Finance as recommendations for the 2016 Federal Budget.

1. *Providing Canadians with tax relief on over-the-counter medicines*

J&J recommends that select consumer health products be made eligible for the Medical Expense Tax Credit (METC) or exempted from the GST. The cost to government for eligibility under the METC would be $38 million, while the cost of relief on these products from the GST would be $75 million.

Health policy in Canada recognizes the growing importance of responsible self-care as an important contributor to the health and productivity of Canadians and the sustainability of our healthcare system. For example, there is broad consensus that Canadians should strive to stop smoking. Proven and recommended Health Canada approved treatments like Nicotine Replacement Therapy are essential self-care options that are subject to provincial and federal taxation. The added out of pocket costs for these products to Canadians is a barrier to their appropriate use and creates an additional inequity for those of lower socioeconomic standing.

Canadians who practice responsible self-care free up space in the health system for those who need it most. Continuing the example above, a recent CIHI report highlighted that 80% of COPD deaths are attributable to smoking, and over the past decade the inequity in smoking rates has actually increased. If all Canadians experienced the same low rates of hospitalization for COPD as the highest income earners, there would be more than 18,000 fewer hospitalization, which translates into $150 million in health sector savings annually, in addition to productivity gains realized by a healthier workforce.

That said, our current system encourages patients with minor ailments to see a doctor for a prescription rather than go to the pharmacy for a product that is often available over-the-counter because the prescription may be refundable, all or in-part. This behaviour results in unnecessary expense to our healthcare system, rewarding visits to a doctor's office for a prescription, instead of making a trip to the pharmacy.

Implementing this tax relief would ensure more dollars remain in the pockets of Canadians, while freeing up precious resources to be better deployed elsewhere in our healthcare system. Further information on this proposed incentive can be found in this year's pre-budget submission by Consumer Health Products Canada.

2. *Support for consumer education programs to ensure the safe use of medicines*

J&J recommends that the federal government provide funding to Health Canada and/or the Public Health Agency of Canada to support the development and dissemination of consumer education programs to ensure the safe use of medicines, including over-the-counter and consumer health products. Providing information to Canadians in plain language and in an easily accessible format

such as www.healthycanadians.gc.ca helps to provide education on the safety of the health products Canadians are using and information on how to use those products effectively.

This would also complement the ongoing Regulatory Transparency and Openness Framework initiatives, providing information and empowering Canadians to be more responsible for their own health care. Existing tools accessible through the Framework, such as the Drug and Health Product Register, are focused on drug products, leaving an information gap for over-the-counter and consumer health products. The Drug Product Database provides regulatory information, but is not consumer-friendly and does not provide information on how to use medicines safely and effectively. The programming recommended would be focused primarily on the consumer as the target audience, and provide plain language information to inform and educate Canadians on the safe use of the medicines they use to manage their health care.

3. *International Trade and Intellectual Property Protection for Pharmaceuticals*

The importance of globally competitive intellectual property (IP) protection for Canada cannot be underestimated. A strong domestic IP regime for pharmaceuticals enables Canadian biopharmaceutical companies to compete more effectively for global R&D investments within their global parent companies.

The enhancements to Canada's IP regime as a result of completing the Canada-European Union Comprehensive Economic and Trade Agreement (CETA) in the areas of Right of Appeal and Patent Term Restoration, are important changes to bringing Canada's IP environment in line with that of our competitors in the EU and the US. We are satisfied that these improvements to intellectual property for pharmaceuticals were subsequently secured in the recently-concluded Trans-Pacific Partnership agreement.

However, the gains made through trade relationships must not be offset by risks posed by changes to the existing domestic framework. While supportive of the amendments to the *Food and Drugs Act* contained in Bill C-17, J&J is concerned that without further guidance and clarification the new authorities, in particular section 21.1– *Power to require and disclose information* of the amended Act, will compromise the protection and handling of confidential business information ("CBI") and jeopardize Canada's ability to meet its international trade obligations.

In particular, without further guidance, the new powers in section 21.1 regarding CBI are inconsistent with both the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS") and the North American Free Trade Agreement ("NAFTA"). Under these treaties, Canada must safeguard confidential information against disclosure, except where "necessary to protect the public" or unless steps are taken to ensure that it is protected against unfair commercial use. Without further restrictions, the new powers are overly broad and allow for disclosure of CBI in a range of circumstances beyond those where disclosure is "necessary to protect the public", and do so without any measures to ensure that disclosed information is protected against unfair commercial use.

Moreover, international treaties further mandate that legal persons shall have the ability to protect trade secrets. Without further guidance, the new powers regarding CBI remove the ability for manufacturers of therapeutic products to protect their trade secrets from disclosure by Health Canada. As such, Health Canada's proposed *Guide to New Authorities* should make clear that the power to disclose confidential business information does not include trade secrets. Providing an exception for trade secrets will not impact the disclosure of safety information, and therefore will not undermine the goals of the new provisions.

In addition, intellectual property protection, through the form of data protection, impacts moving products from prescription drug status to non-prescription status and increasing self-care product choice for Canadians. At present, Canada does not provide market incentives or data protection for consumer health product companies that use proprietary data to support prescription to non-prescription switches or innovative health claims. When paired with an interpretation of the World Trade Organization Technical Barriers to Trade agreement imposes an unnecessary delay of six months for switching products from prescription to non-prescription status, the result is a regulatory system which is not competitive internationally and discourages innovation.

J&J recommends that the federal government adopt a 2-stage switch process allowing 'product based' vs. 'ingredient based' switches thereby providing a period of exclusivity during the WTO notification period and adopt appropriate and competitive data protection provisions as part of the forthcoming non-prescription drug regulatory framework. This will empower Canadians who use self-care to manage their health while encouraging innovation in consumer health products.

4. *Capturing the Full Value of Medicines to the Health of Canadians*

Today, thanks in large part to biomedical innovation, people around the world are living longer, healthier and more productive lives than ever before. In fact, between 1986 and 2000, 40% of the improvement in life expectancy has been due to innovative medicines.

More recently, innovative medicines are estimated to have contributed to 73% of improvement in life expectancy between 2000 and 2009 once other factors are taken into account (e.g. income, education, immunization, reduction in risk factors, health system access).

New medicines are offering real hope to patients facing even the most serious diseases:

- Since 1980, 83% of life expectancy gains for cancer patients are attributable to new treatments, including medicines. Today, two out of three people diagnosed with cancer survive at least five years, compared to just one of three in 1964.
- Thanks in part to new medicines, the death rate for cardiovascular disease fell 33% between 1999 and 2009.
- The progress made fighting HIV/AIDS over the past several decades means that today, a 20-year-old diagnosed with HIV and treated appropriately can expect to live into his or her seventies.

For healthcare systems focused on improving population health at sustainable costs, innovative medicines can represent exceptional value – both in lives saved and in improving health while bringing down expenses in other parts of the healthcare system, such as hospitalization. However, the public dialogue around pharmaceutical innovation has focused largely on the cost of purchasing drugs rather than the cost of disease, including diagnosis, treatment, hospitalization, and care.

The debate about the value and price of medicines taking place today has potentially meaningful consequences for a pharmaceutical innovation model that has delivered exceptional advances for patients over the past decades. Pharmaceutical innovators – including Janssen, a member of the J&J Family of Companies – are actively engaging in the global dialogue on value, access and affordability, and price. We must establish a common understanding of the cost of disease and the assessment of the value of innovative medicines; identify and advance solutions that will result in more people in more places having access to transformational medicines; and ensure that we can continue to attract investment to biomedical research that will enable us to win battles against devastating diseases in the future.

Research Infrastructure

Critically, clinical trials are where much of our development investments have direct impacts and benefits for Canadians. Canadian patients and healthcare providers deserve first access to new life-saving treatments and this is often facilitated through clinical trials.

The federal government's recent support of the Canadian Clinical Trials Coordinating Centre (CCTCC) holds considerable promise to improve Canada's competitiveness in conducting clinical trials. CCTCC is a collaborative effort of the Canadian Institutes of health Research (CIHR), Innovative Medicines Canada (formerly Rx&D), and the Association of Canadian Academic Healthcare Organizations (ACAHO) that aims to facilitate research cooperation and streamline and expedite administrative processes to make Canada more attractive for multi-centre trials. We believe that we must accelerate public-private collaborations to sustain and attract clinical trials to Canada in the face of increasing global competition for these key investments. J&J recommends that the federal government monitor this work closely and enhance resources and support for clinical trials wherever possible.

Measuring R&D Impact

Each year, the Patented Medicines Prices Review Board (PMPRB) reports the R&D investment of patented pharmaceutical companies, such as Janssen, a member of the J&J Family of Companies, as a percentage of sales. The PMPRB, by definition of its mandate, only reports R&D that meets the strict criteria of the Scientific Research & Experimental Development (SR&ED) tax incentive program. While SR&ED is an important program designed to help attract and support investment in the life sciences sector, it is not inclusive of many important scientific innovation investments we make in Canada.

For Janssen, a number of important investments are not SR&ED eligible and, therefore, are not captured annually by the PMPRB report. As a result, Canada's reporting does not accurately reflect the innovation and investment made by patented pharmaceutical companies in Canada, hampering

our competitiveness in attracting global R&D. We request that annual reporting of R&D investment in Canada by the PMPRB be broadened to truly evaluate and reflect the actual investment footprint of our biopharmaceutical industry in Canada.