GOVERNMENT RESPONSE:

Mr. Sean Casey, M.P.
Chair, Standing Committee on Health
House of Commons
Ottawa, Ontario
K1A 0A6

Dear Mr. Casey,

On behalf of the Government of Canada (Government), I am pleased to present you with the Government Response to the Sixteenth Report of the Standing Committee on Health, entitled *Strengthening the Oversight of Breast Implants*.

I would like to thank you and the Committee for the comprehensive study on the safety of breast implants and the associated recommendations. These recommendations highlight the ongoing need to maintain and continue to improve effective oversight over medical devices, including the monitoring of their safety once they are available on the Canadian market. The health and safety of Canadians is a top priority for the Government of Canada.

I would also like to thank the brave Canadians with lived experience who shared their testimony during the Committee's study. Communication of their experiences has resulted in tangible improvements in the information that is now available to people who are considering breast implants. The Government acknowledges that some people with breast implants have experienced a negative impact on their health and their quality of life. We will continue to take their testimony into consideration as we work on a path forward.

The world of medical devices is constantly evolving and the safety of medical devices in Canada is a shared responsibility. We continue to adapt our approach so that Canadians may continue to have confidence in their medical devices and have the information that they need to make informed decisions about their health and well-being.

As the Committee indicated in its report, the concept of a breast implant or a medical device registry has been discussed for many years. While there is significant interest in establishing a registry, there are also important considerations that will guide how a registry may be implemented in our country.

The provinces and territories administer and deliver most of Canada's health care services, and different privacy laws for health information may apply across various jurisdictions. The design and implementation of a registry that includes personal health information, such as a breast implant registry, will require the participation of various health authorities, all of whom would have roles to play.

In acknowledgment of the federal role, Health Canada has taken steps to further identify, assess and manage risk associated with breast implants and will continue to play a key role in engaging with people with lived and living experience, experts, and other stakeholders to facilitate exploring potential options for a breast implant registry.

For example, Health Canada published an Action Plan on Medical Devices in 2018 to strengthen regulatory oversight of all medical devices, the outcomes of which included:

- Publication of regulations for mandatory reporting by hospitals, and strengthened post-market surveillance of medical devices;
- Establishment of the Scientific Advisory Committee on Health Products for Women to provide Health Canada with timely scientific, technical and patient-centered advice on current and emerging issues regarding women's health; and
- Increased transparency for Canadians through publication of searchable public web portals with medical device clinical data, pre-market regulatory decision summaries,

incidents, and inspections.

Health Canada also completed actions specific to breast implants, including suspending the medical device authorization for Allergan's Biocell (macro-textured) breast implants, which are associated with the risk of developing a rare form of cancer, and implementing comprehensive labelling changes to inform decision-making, including patient decision checklists. The Department continues to monitor for new or increasing risks associated with breast implants and update safety information on breast implants as needed to support decision-making among health care professionals and patients.

The Government Response below addresses the Committee's recommendations and highlights related initiatives that are currently underway. As recommendations 1 to 6 are all related to the development and implementation of a breast implant registry, the Response provides a single response for this theme that is grounded in the recommendation to establish a Committee. The response also reaffirms the Government's intention to continue to advance related activities that support medical device safety and informed decision making.

Theme 1: Establishment of a Breast Implant Registry (Recommendation 1 to 6)

The Report recommends that the Government, as soon as possible, establish a national breast implant registry that would allow breast implant recipients to receive information in the event of a recall, enable the collection of comprehensive risk and benefits data, as well as track the safety of breast implants in the long term, including patient-reported outcomes and other devices implanted at the same time as the breast implants. The reports also recommends that the registry collects data via a mandatory informed consent form signed by the surgeon and patient, that the patient should be offered the option to opt out of the registry, and that the registry be funded under a cost-recovery model funded by breast implant manufacturers.

To date, there is only one national medical device registry in Canada, the Canadian Joint Replacement Registry, managed by the Canadian Institute for Health Information (CIHI). This voluntary medical device registry is based on existing administrative health data from public institutions and cannot facilitate contacting individual patients in the event of a recall.

In March 2023, Health Canada, along with the Canadian Institutes of Health Research (CIHR) and Women and Gender Equality Canada as federal partners, participated in a Best Brains Exchange meeting that examined the development of a registry to capture nation-wide information about the effects of breast implants on an ongoing manner. International and domestic stakeholders from across the health care ecosystem participated in the discussion.

The key challenges identified in the establishment of a breast implant registry relate to the governance of health data, including data sharing, use, and publication.

Unlike in some of the international jurisdictions that have implemented medical devices registries, in Canada, provinces and territories are the custodians of health data and different federal or provincial privacy laws may apply. A national breast implant registry would require a high degree of coordination.

This is further complicated by the inclusion of health data from private health care institutions, which are where most people receive their breast implants. To facilitate contacting people in the event of a recall, the collection of personal health data will be required, and security of this information will be paramount.

The Report recommends that the Government quickly establish a committee made up of officials from Health Canada, experts and patient representatives, and work with provinces and territories to support the goal of a registry (Recommendation 2). The Government recognizes the need to identify solutions for the development and implementation of a national breast implant registry in Canada and believes that establishing a committee with the required

expertise and knowledge to identify solutions is the best next step. The Government will continue engaging with stakeholders, including provincial and territorial governments, to explore potential options for a breast implant registry.

The committee will be established in a timely manner to assess options and implementation considerations relating to recommendations 1 and 3 to 6, including establishing a registry that enrolls patients by default, with the option to opt out (Recommendation 3); establishing an informed-consent form with a clear checklist that identifies the risks of breast implants (Recommendation 3); options for funding models, including a cost-recovery model funded by breast implant manufacturers (Recommendation 4); tracking of other devices, such as mesh, implanted alongside breast implants, along with patient-reported outcome measures (Recommendation 5); and how to best develop and implement data standards, alongside CIHI (Recommendation 6).

Discussions regarding the creation of a registry will involve experts, people with lived and living experience, health authorities and organizations, and provincial and territorial governments, all of whom have roles to play. The Committee will be expected to provide recommendations and advice to Health Canada to fulfill the recommendation that the Government of Canada establish a national breast implant registry (Recommendation 1).

Theme 2: That the Government of Canada facilitate the process of reporting adverse events to Health Canada and extend the obligation to private practices. (Recommendation 7)

The Government acknowledges this recommendation. In December 2019, the Government began requiring hospitals to report medical device incidents and serious adverse drug reactions. The reports submitted by hospitals are a valuable source of information for the monitoring of health products. Reports from various sources, including hospitals, help influence Health Canada's surveillance activities and subsequent safety reviews, advisories, and recall actions on health products. Health Canada has conducted activities to encourage hospital reporting, such as publishing education modules and articles for health care professionals.

The Report recommended extending mandatory reporting of adverse events to private practices as the majority of breast implant surgeries are performed in private clinics in Canada. Health Canada encourages people with breast implants and their health care providers to report problems related to the use of these breast implants and has published a reporting page on the Health Canada website and through its fact sheet to streamline reporting.

The Canadian health care system is under significant stress following the COVID pandemic and may benefit from additional time to fully implement the mandatory reporting framework. Considerations related to the expansion of the mandatory reporting in private clinics would require additional people, new policies, and technological solutions to implement in partnership with provinces and territories. The Government will continue to explore options to gather information from any available source, including private clinics, with patient safety as the priority.

Theme 3: That the Government of Canada publish, on its website, clear and comprehensive information on the risks associated with the different types of breast implants, as well as photographs showing the adverse effects of breast implants. (Recommendation 8)

The Government agrees with this recommendation and agrees that access to trusted information related to breast implants is essential to support informed consent. Health Canada has published information for Canadians in a variety of formats, including a comprehensive webpage on breast implants; a data blog updated annually which outlines the findings of a rare form of cancer associated with certain breast implants; and social media posts on Instagram, Facebook, X (formerly known as Twitter), and LinkedIn.

Furthermore, Health Canada requires manufacturers to make comprehensive information about the risks available to people considering breast implants, including a patient decision checklist. To complement information from the manufacturer, the Department most recently published a fact sheet on breast implants to outline key risks, inform people where they may obtain comprehensive information, and includes a list of questions informed by people with lived and living experience to discuss with their surgeon. Finally, the Department introduced a subscription service to inform interested Canadians about new Health Canada publications on breast implants, such as new safety information.

Health Canada will continue to provide information on breast implants to support informed decision-making. Moving forward, this will include the addition of photographs showing adverse effects related to breast implants on its website. This would provide additional information on potential symptoms for people to be aware of, which supports follow-up with health care professionals as needed.

Theme 4: That Health Canada recognize breast implant illness. (Recommendation 9)

The Government acknowledges this recommendation and is currently finalizing a review on breast implant illness. Health Canada continues to monitor safety of medical devices, including breast implants, to identify and assess potential harms. This monitoring includes the scanning of multiple sources of information (reports of adverse reactions, new safety information from foreign regulators, and medical and scientific literature) to identify potential medical device safety issues. As part of this ongoing work, Health Canada is performing a scientific, evidence-based review of breast implant illness, which is a term used to describe a variety of symptoms associated with breast implants. Once finalized, the Department will publish its findings on the website, which is planned to occur in Spring 2024.

Theme 5: That the Government of Canada fund research on breast implants, including, but not limited to, long-term health effects. (Recommendation 10)

The Government agrees that additional research would better inform clinicians, researchers, and patients about the benefits and risks of breast implants. The Government has provided support to several research projects through the Canadian Institutes of Health Research (CIHR). As the federal investment agency for health research, CIHR invests in all areas of health, including women's health. Under the leadership of its Institute of Gender and Health, CIHR is also an international leader in fostering research that explores how sex and gender influence health.

Notably, the National Women's Health Research Initiative, led by CIHR in partnership with Women and Gender Equality Canada, is advancing a coordinated research program that addresses under-researched and high-priority areas of women's health. Through this initiative, CIHR launched a funding opportunity in December 2023 to support translational research in health care diagnostics, therapeutics, and devices, which has the potential to advance research related to breast implants.

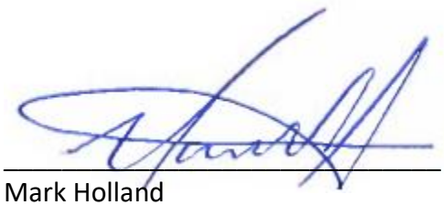
Previously, in 2020, CIHR invested in a research project led by Dr. Anna Gagliardi, from the University Health Network, in partnership with Health Canada to explore if the department could improve decisions about licensing of devices (i.e., breast implants, pacemakers, joints, birth control devices) by applying a sex- and gender-based plus analysis. This research identified several recommendations regarding the inclusion of sex, gender and intersectional details of persons included in studies that test device safety and in reports of device-related problems, which may result in greater safety.

In addition, CIHR contributes to building capacity in the next generation of researchers. This includes awards to graduate students to support them as they carry out research in this area, such as studying the mechanisms underlying capsular contracture, a common complication of breast implant surgery, particularly following radiotherapy. Other examples include assessing new models of care to improve recovery for breast cancer patients undergoing autologous breast reconstruction. There may be future opportunities for CIHR to fund additional research into breast implants, including long-term health effects, within its existing resources.

Conclusion

The Government is committed to continue to prioritize actions that will improve access to information relating to breast implant safety in Canada. In addition, the Government will continue to seek input from people with lived and living experience to inform these actions.

Once again, I would like to thank you, Mr. Casey, and all members of the Standing Committee on Health for this Report and its recommendations.



Mark Holland
Minister of Health