# RESPONSE TO PETITION

Prepare in English and French marking 'Original Text' or 'Translation'

PETITION NO.: **421-03410**

BY: **MR. STANTON (SIMCOE NORTH)**

DATE: **APRIL 11, 2019**

PRINT NAME OF SIGNATORY: **PAM DAMOFF**

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Response by the Minister of Health

SIGNATURE
Minister or Parliamentary Secretary

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SUBJECT

**Medical devices**

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**ORIGINAL TEXT**

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**REPLY**

The health and safety of Canadians is a top priority for the Government of Canada. The world of medical devices is constantly evolving. We are working to ensure that our regulations and guidance keep pace so that Canadians can continue to have confidence in their medical devices, and the information that they need to make informed decisions about their health and well-being.

Breast implants are regulated in Canada as Class IV medical devices (the highest risk classification). Manufacturers of breast implants are required, as per the Medical Device Regulations (MDR), to demonstrate the safety and effectiveness of their products prior to them being licensed for sale in Canada. They are also required to monitor the safety and effectiveness of these products once they are on the market.

Health Canada's decision to issue medical device licences to silicone gel-filled breast implants followed a lengthy and thorough scientific review. The decision was informed by a wide range of sources, including medical and scientific publications, and the reports of three independent scientific panels. Since then, Health Canada has been proactive in informing patients and surgeons about the risks associated with breast implants (https://www.canada.ca/en/health-canada/services/drugs-medical-devices/breast-implants.html?wbdisable=true). The Department has published

information on its website to better inform patients, including several information updates and an It's Your Health article (https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/hl-vs/alt_formats/pacrb-dgapcr/pdf/iyh-vsv/med/implants-eng.pdf).

In 2017, the Government of Canada conducted a safety review of the risk of Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) related to breast implants. We released a safety communication to patients and healthcare professionals to provide information on signs and symptoms, testing steps to recognise and diagnose BIA-ALCL, and treatment options. This review also resulted in:

- strengthened product labelling on the risk of BIA-ALCL; and,
- conditions added to the breast implant licenses for manufacturers to annually submit all known cases of BIA-ALCL along with a detailed analysis of the scientific literature on BIA-ALCL.

The Department oversaw labelling updates to breast implants in the summer of 2018 to include newly-identified risks, and to capture additional details regarding BIA-ALCL. We continue to ensure that safety information on breast implants is updated in order to support decision-making among healthcare professionals and patients. In addition, manufacturers are not only required to report suspected and confirmed cases of BIA-ALCL to Health Canada annually as part of the conditions of licencing, but they are also required to report any serious incidents of which they are aware, as required under the MDR.

During a second safety review that began in 2018 exploring the risk of BIA-ALCL, Health Canada noted a significant increased risk associated with macro-textured breast implants. In 2019, the department took prompt action and signalled to Allergan (the manufacturer of Biocell, the only macro-textured breast implants on the Canadian market) its intent to suspend the products from the Canadian market within 15 calendar days (by April 19) unless Allergan could provide data to support the safety of their products. The data submitted by Allergan is currently being reviewed by Health Canada.

Health Canada has also initiated another safety review focussing on systemic symptoms such as rheumatic and autoimmune disorders. The results of this safety review will be made public in summer 2019. Appropriate and timely action will be taken if and when any new health risks are identified.

Health Canada continues to be committed to openness and transparency in licencing decisions. A Summary Basis of Decision document, available online (https://hpr-rps.hres.ca/reg-content/summary-basis-decision-detailTwo.php), outlines the information provided and evaluated in a submission. Since the beginning of March 2019, Health Canada has released additional clinical information provided by the manufacturer to support their application on this website. Although some manufacturing details might fall under proprietary information, additional details may be released through the Access to Information process.

Health Canada is also undertaking a number of activities to support non-biased, evidence-based discussions on breast implants which include meaningful patient representation and input.

For example, Health Canada has recently formed the Scientific Advisory Committee (SAC) on Women's Health, which will be addressing, among other items, issues related to breast implants. The first committee meeting will take place in Ottawa in May 2019. The agenda for this inaugural meeting will include an examination of:

- clinical evidence requirements for medical devices;
- lifecycle management of medical devices (including a case study on mesh implants); and,

- knowledge transfer to patients (including a case study on breast implants).

Health Canada recommends that people with a breast implant should speak to their surgeon about the type of breast implant received, do regular breast self-exams, and see a healthcare professional for regular follow-up. If there are unusual changes to their breasts, including pain, sudden swelling or a lump, Health Canada recommends that people with a breast implant contact a healthcare provider.

People who are considering a breast implant are also encouraged to get the information needed to make an informed decision, and to consult with a healthcare professional about the risks and benefits associated with breast implants, prior to undergoing the procedure.

Healthcare professionals should provide patients with the appropriate information about the benefits and risks of their options, including the risk of BIA-ALCL, so that patients can make an informed decision. Patients should stay informed about the signs and symptoms of BIA-ALCL and consult their healthcare professional if they experience any unusual changes to their breasts. Healthcare professionals should be aware of testing used to recognize and diagnose BIA-ALCL, and report any incidents of BIA-ALCL to Health Canada.

Health Canada will take prompt action and will inform healthcare professionals and the public if there are changes to the safety of breast implants.