

Date

Regulator Name OR Department Name

Regulator Address Line 1

Regulator Address Line 2

Regulator Address Line 3

Regulator Address Line 4

Regulator Address Line 5

Dear _____ **OR** To whom it may concern;

I am writing regarding the issue of migrated silicone from silicone gel breast implants.

Health Canada's mandate is to protect the well-being and health of Canadians, and to ensure reasonable safety of the devices it licenses.

Health Canada currently accepts industry claims that the risks and long-term impact of migrated silicone within the human body have not been established. REAL WORLD EVIDENCE demonstrates that migrated silicone causes illness, pain and death. Migrated silicone has been empirically documented over decades.

It is a contradiction to deem silicone gel breast implants 'safe' while at the same time stating that the long-term impact to women with migrated silicone remains unknown. Migrated silicone is a huge health problem for women like me who have or have had silicone breast implants. After nearly 60 years, failure to definitively establish impact can no longer be tolerated. Health Canada must take immediate action to protect Canadians.

I have previously filed an Adverse Events Report. ***OR*** I have not yet filed an Adverse Events Report, but plan to do so.

I would be interested in offering myself as a study participant, in studies that include women already harmed through migrated silicone.

I ask that your responsibility as Canada's regulatory authority be met with expedient, concrete actions in terms of research and solutions to treat the silicone deposits that remain trapped in women's bodies (that remain trapped in my body), and to understand the long term impact to health. And that you take immediate regulatory actions that require industry accountability.

I request that Health Canada take immediate action to:

- Require that unbiased studies using participants already diagnosed with migrated silicone be created to determine the short term and long term impacts of migrated silicone

- Urgently put together a team of independent researchers to find remedial solutions for residual migrated silicone
- That Health Canada will provide information and direction to consumers and Health Care professionals regarding (recourse for) migrated silicone.
- That Health Canada ensures a protocol of medical care is in place for migrated silicone and gel bleed prior to licensing or relicensing the product, and using the option of revoking existing licenses.
- That Health Canada serves manufacturers with a non-compliance warning letter regarding the long term safety of migrated silicone. The warning letter must include a regulatory consequence of product recall and FIRM compliance date. Health Canada must STOP the endless 'do-overs' provided manufacturers over decades in regard to long term safety data.

I request confirmation of receipt of my letter and follow-up regarding steps Health Canada will take to address these critical issues.

Sincerely,

Your Name
Your Address Line 1
Your Address Line 2
Your Phone number
Your Email

