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STRENGTHENING THE OVERSIGHT OF BREAST IMPLANTS

Report of the Standing Committee on Health

Sean Casey, Chair

NOVEMBER 2023
44th PARLIAMENT, 1st SESSION

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NOTICE TO READER

Reports from committees presented to the House of Commons

Presenting a report to the House is the way a committee makes public its findings and recommendations on a particular topic. Substantive reports on a subject-matter study usually contain a synopsis of the testimony heard, the recommendations made by the committee, as well as the reasons for those recommendations.

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THE STANDING COMMITTEE ON HEALTH

has the honour to present its

SIXTEENTH REPORT

Pursuant to its mandate under Standing Order 108(2), the committee has studied oversight of medical devices (breast implants) and has agreed to report the following:

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SUMMARY

Health Canada regulates breast implants as class IV medical devices, the category representing the highest risk. Breast implants are associated with a wide range of adverse effects, including a type of cancer of the immune system known as “breast implant-associated anaplastic large cell lymphoma.” For decades, the federal government has been called upon to make regulatory changes to enhance the safety of breast implants, yet important gaps remain in the oversight of these devices. Breast implant recipients continue to be insufficiently protected from adverse outcomes. The House of Commons Standing Committee on Health undertook a study to follow up on the improvements put in place as part of Health Canada’s 2018 action plan on medical devices, as well as to assess the feasibility of the creation of a central breast implant registry. The committee heard strong support from plastic surgeons, researchers and patient advocates for the creation of a national breast implant registry. Such a registry would improve the traceability of implants, facilitate recalls and advance research related to breast implants. Other concerns identified during the study include shortcomings in the process for reporting adverse effects to Health Canada, deficiencies in the safety information Health Canada presents to consumers, as well as a lack of research on breast implants. Gender inequity within the health care system was cited as one of the reasons why women’s experiences with breast implants have been historically overlooked.

The federal government should take immediate action to protect the health and safety of those who have received or are considering getting breast implants. In this report, the committee puts forward 10 recommendations on how the Government of Canada can strengthen the oversight of breast implants. Notably, the committee recommends that the federal government establish a national breast implant registry as soon as possible, require private practices to report adverse events, invest in research on breast implants, and make improvements to Health Canada’s website to better inform consumers about the risks of these medical devices.

LIST OF RECOMMENDATIONS

As a result of their deliberations committees may make recommendations which they include in their reports for the consideration of the House of Commons or the Government. Recommendations related to this study are listed below.

Recommendation 1

That, as soon as possible, the Government of Canada establish a national breast implant registry that would allow:

- **breast-implant recipients to receive information and be contacted in the event of a recall;**
- **reliable and comprehensive data on the risks and benefits of breast implants to be collected; and**
- **the long-term safety of these devices to be proactively tracked. 19**

Recommendation 2

That the Government of Canada quickly establish a committee made up of officials from Health Canada, experts and patient representatives, and work with provinces and territories to achieve this goal. 19

Recommendation 3

That the Government of Canada ensure that the national breast implant registry is implemented via a mandatory, uniform informed-consent form that has a clear checklist, that is signed by the surgeon and patient, and that offers the patient the possibility of opting out of the registry. 20

Recommendation 4

That the Government of Canada ensure that the national breast implant registry has stable and long-term funding, that the registry uses a cost-recovery model, and that the costs are funded by breast implant manufacturers. 20

STRENGTHENING THE OVERSIGHT OF BREAST IMPLANTS

INTRODUCTION

Calls for better oversight of breast implants in Canada stretch back decades. Since 2004, multiple bills have been introduced in Parliament to establish a national breast implant registry, but none have progressed beyond first reading.[1] In 2006, the House of Commons Standing Committee on Health (the committee) published a report on silicone gel-filled breast implants.[2] The report identified several areas of concern regarding the oversight of these implants in Canada and made recommendations to the Government of Canada on safety assessments, special access, informed consent and post-approval surveillance.

Certain changes were later made to the oversight of medical devices. In 2014, the *Protecting Canadians from Unsafe Drugs Act* (*Vanessa's Law*) was enacted to improve the safety of drugs and medical devices. Among the measures implemented by *Vanessa's Law* is the requirement for hospitals to report incidents involving medical devices.[3] In 2018, Health Canada published an action plan on medical devices, with the aim of improving safety, effectiveness and quality.[4] As part of this plan, the department established a Scientific Advisory Committee on Health Products for Women (SAC-HPW)[5] and extended mandatory incident reporting to medical device manufacturers.[6]

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1 Bill C-507, An Act to establish and maintain a national Breast Implant Registry, 37th Parliament, 3rd Session; Bill C-419, An Act to establish and maintain a national Breast Implant Registry, 38th Parliament, 1st Session; Bill C-312, An Act to establish and maintain a national Breast Implant Registry, 39th Parliament, 1st Session; Bill C-312, An Act to establish and maintain a national Breast Implant Registry, 39th Parliament, 2nd Session; Bill C-366, An Act to establish and maintain a national Breast Implant Registry, 40th Parliament, 2nd Session; Bill C-366, An Act to establish and maintain a national Breast Implant Registry, 40th Parliament, 3rd Session; Bill C-255, An Act to establish and maintain a national Breast Implant Registry, 41st Parliament, 1st Session; Bill C-255, An Act to establish and maintain a national Breast Implant Registry, 41st Parliament, 2nd Session.

2 House of Commons Standing Committee on Health (HESA), *Silicone gel-filled implants: areas of concern*, Third Report, 39th Parliament, 1st Session.

3 *Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)*, S.C. 2014, c. 24.

4 Government of Canada, *Health Canada's Action Plan on Medical Devices: Continuously Improving Safety, Effectiveness and Quality*, December 2018.

5 Government of Canada, *Scientific/Expert Advisory Committees, Health Products for Women*.

6 *Regulations Amending the Food and Drug Regulations and the Medical Devices Regulations (Post-market Surveillance of Medical Devices)*, SOR/2020-262, Part II, Vol. 154, No. 26, 4 December 2020, pp. 3822–3872.

Despite these initiatives, many of the issues identified in the committee's 2006 report persist. Canada still does not have a national breast implant registry. The safety of breast implants, informed consent prior to implantation and the post-market surveillance of implants remain areas of concern. In light of this situation, the committee, on 9 February 2022, adopted a motion to study the oversight of breast implants. The motion read, in part:

> That, pursuant to Standing Order 108(2), the committee undertake a study to follow up on the improvements that have been put in place to tighten Health Canada's rules and improve oversight of medical devices (breast implants) in 2018 and assess the feasibility of establishing a central breast implant traceability registry that would make it mandatory for practitioners who implant, remove, or replace breast implants to enter certain data into the registry.[7]

The committee held four meetings on this study between 25 April 2023 and 11 May 2023 and heard from 11 witnesses. Witnesses included government officials representing Health Canada, the Canadian Institute for Health Information (CIHI) and the Canada Health Infoway, as well as plastic surgeons, professional associations, researchers and patient advocacy groups. In addition, the committee received 42 written briefs.[8]

This report discusses certain key themes that emerged from the testimony: the need for a national breast implant registry; the optimal design for such a registry; concerns over pre- and post-market vigilance of breast implants; inadequate consumer information and informed consent; the need for further research on breast implants; and issues of gender equity and body image. The report also offers the federal government recommendations on how to strengthen the oversight of breast implants.

7 HESA, *Minutes of Proceedings*, 9 February 2022.

8 HESA, Briefs, *Oversight of Medical Devices (Breast Implants)*.

THE NEED FOR A NATIONAL BREAST IMPLANT REGISTRY

The committee heard strong support from witnesses for the creation of a national breast implant registry.[9] Witnesses generally expressed dismay that no such registry exists in Canada, despite repeated calls to action spanning more than 30 years.[10] Canada was said to be the only G7 country without a breast implant registry.[11] A number of witnesses indicated that a registry is necessary to improve traceability, facilitate recalls and advance research related to breast implants.

According to the testimony, breast implant recipients comprise an estimated 3% to 4% of women in Western countries.[12] Around 70% of those with implants had the surgery for cosmetic reasons.[13] The remainder have implants for medical reasons, such as reconstruction after mastectomy or gender-affirming surgery. The committee heard how the lack of a registry leaves breast implant recipients insufficiently protected from potential adverse outcomes associated with these devices.

Health Canada categorizes breast implants as Class IV medical devices, representing the highest risk to health.[14] According to the department, breast implants are associated with a variety of risks and adverse events that range from minor to life-threatening, such as:

- post-operative complications (e.g., swelling, bleeding, mild to serious infection, and changes in nipple and/or breast sensation);

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9 HESA, *Evidence*, 4 May 2023, 1105 (Dr. Peter Lennox, Clinical Professor, Division of Plastic Surgery, The University of British Columbia, as an individual); HESA, *Evidence*, 4 May 2023, 1105, 1110 (Dr. Stephen Nicolaidis, Assistant Professor of Surgery, Université de Montréal, as an individual); HESA, *Evidence*, 9 May 2023, 1105 (Dr. Jan Willem Cohen Tervaert, Professor of Medicine, University of Alberta, as an individual); HESA, *Evidence*, 9 May 2023, 1115 (Dr. Steven Morris, President, Canadian Society of Plastic Surgeons); HESA, *Evidence*, 9 May 2023, 1115 (Dr. Lorraine Greaves, Chair, Scientific Advisory Committee on Health Products for Women); HESA, *Evidence*, 11 May 2023, 1120 (Nancy Pratt, Patient Advocate, Breast Implant Failure and Illness Society Canada); HESA, *Evidence*, 11 May 2023, 1105 (Julie Elliott, Patient Advocate, Breast Implant Safety Alliance).

10 HESA, *Evidence*, 9 May 2023, 1110 (Dr. Steven Morris); HESA, *Evidence*, 11 May 2023, 1120 (Nancy Pratt); HESA, *Evidence*, 9 May 2023, 1115 (Dr. Lorraine Greaves).

11 HESA, *Evidence*, 4 May 2023, 1105 (Dr. Peter Lennox).

12 HESA, *Evidence*, 9 May 2023, 1105 (Dr. Jan Willem Cohen Tervaert).

13 HESA, *Evidence*, 9 May 2023, 1105 (Dr. Jan Willem Cohen Tervaert).

14 HESA, *Evidence*, 25 April 2023, 1205 (David Boudreau, Director General, Medical Devices Directorate, Health Products and Food Branch, Department of Health). Medical devices are classified into one of Classes I to IV, where Class I represents the lowest risk and Class IV represents the highest risk.

- the need for additional surgeries to address dissatisfaction with the size or shape of the implant(s) or treat an adverse event following the initial procedure;
- incorrect positioning of the implant;
- implant rupture (i.e., the implant shell breaks or tears);
- capsular contracture (i.e., the scar tissue around the implant tightens or hardens); and
- breast implant-associated anaplastic large cell lymphoma (BIA-ALCL), a rare type of non-Hodgkin's lymphoma that can develop next to the implant.[15]

In some cases, BIA-ALCL has resulted in death. The committee heard that 3 deaths from BIA-ALCL have been reported in Canada, and 36 have been reported globally.[16]

In 2022, the United States Food and Drug Administration and Health Canada both published information on reports of other cancers, including squamous cell carcinoma and various lymphomas, found in the scar tissue that forms around breast implants.[17]

The committee heard that implants have also been associated with various autoimmune diseases as well as breast implant illness (also known as "autoimmune/autoinflammatory syndrome induced by adjuvants").[18] Dr. Jan Willem Cohen Tervaert, professor of medicine at the University of Alberta, described some of the scientific research in this area.[19] As of the writing of this report, Health Canada's web page on the risks of breast implants makes

15 Government of Canada, *Breast implants: Risks*.

16 HESA, *Evidence*, 4 May 2023, 1125 (Dr. Peter Lennox).

17 United States Food and Drug Administration (FDA), *Breast Implants: Reports of Squamous Cell Carcinoma and Various Lymphomas in Capsule Around Implants: FDA Safety Communication*, 8 September 2022; FDA, *UPDATE: Reports of Squamous Cell Carcinoma (SCC) in the Capsule Around Breast Implants - FDA Safety Communication*, 22 March 2023; Government of Canada, "Other types of cancer near a breast implant," Breast implants: Risks.

18 HESA, *Evidence*, 9 May 2023, 1100, 1105 (Dr. Jan Willem Cohen Tervaert).

19 See, for example: Abdulla Watad et al., "Silicone breast implants and the risk of autoimmune/rheumatic disorders: a real-world analysis," *International Journal of Epidemiology*, Vol. 47, No. 6, December 2018; Jan Willem Cohen Tervaert et al., "Autoimmune/inflammatory syndrome induced by adjuvants (ASIA) in 2023," *Autoimmunity Reviews*, Vol. 22, No. 5, May 2023; Jan Willem Cohen Tervaert et al., "Breast implant illness: scientific evidence of its existence," *Expert Review of Clinical Immunology*, Vol. 18, No. 1, January 2022.

no mention of breast implant illness.[20] An official from Health Canada testified that the department was assessing the issue of breast implant illness and had not yet taken any position on the subject because of a lack of data.[21]

Most of the briefs submitted contained personal stories detailing the negative effects that breast implant complications have had on the authors' health and well-being.[22] The committee expresses deep concern over the profound consequences that women in such circumstances have had to bear. The briefs describe the breadth and depth of symptoms and suffering caused by complications from breast implants. Several recurring themes emerged from the briefs and are summarized in Figure 1. The physical, psychological and financial suffering resulting from those complications was, according to the briefs, prolonged or exacerbated by a lack of information. Many argue that a registry would prevent other women from experiencing similar suffering.

20 Government of Canada, *Breast implants: Risks*, 12 July 2023.

21 HESA, *Evidence*, 25 April 2023, 1115 (David Boudreau).

22 HESA, Briefs, *Oversight of Medical Devices (Breast Implants)*.

Figure 1—Summary of Experiences with Breast Implant Complications, as Described in the Briefs

Source: Figure prepared by the Library of Parliament using HESA, Briefs, *Oversight of Medical Devices (Breast Implants)*.

The traceability of breast implants in Canada is a key concern. The current systems for notifying affected persons of breast implant recalls are, according to some witnesses, insufficient,[23] leaving those who have not been contacted at risk. The committee heard that many women are not notified of recalls or safety alerts that affect them. Julie Elliott, a patient advocate from the Breast Implant Safety Alliance, told the committee how public health authorities failed to contact thousands of women with textured implants to inform them that these implants were associated with a higher risk of BIA-ALCL.[24] She noted that the traceability problem is complicated by the various provincial requirements on how long plastic surgeons must retain patient records, which range from 5 years in Quebec to 16 years in British Columbia. The briefs also highlight the barriers that the patients had encountered in attempting to gain access to their own records.

Several witnesses pointed to the lack of basic information about breast implants in the country.[25] For example, it is unknown how many women in Canada have received implants or experienced safety issues. The committee heard that without this information, it is impossible to properly calculate risk, a discussion of which is needed for informed consent prior to implantation.[26]

Additionally, the testimony highlighted the importance of long-term safety monitoring, because illnesses associated with breast implants can have a long latency period. For example, Dr. Jan Willem Cohen Tervaert testified that the symptoms of breast implant illness tend to occur 7 to 10 years after implantation.[27]

OBJECTIVES OF A NATIONAL BREAST IMPLANT REGISTRY

According to the testimony, a registry would represent a means of:

- providing breast-implant recipients with information and contacting them in the event of a recall;[28]

23 HESA, *Evidence*, 9 May 2023, 1245 (Dr. Jan Willem Cohen Tervaert); HESA, *Evidence*, 9 May 2023, 1245 (Dr. Steven Morris); HESA, *Evidence*, 11 May 2023, 1230, 1245 (Julie Elliott).

24 HESA, *Evidence*, 11 May 2023, 1105 (Julie Elliott).

25 HESA, *Evidence*, 11 May 2023, 1110 (Terri McGregor, Patient Advocate, Breast Implant Safety Alliance); HESA, *Evidence*, 9 May 2023, 1120 (Dr. Lorraine Greaves); HESA, *Evidence*, 4 May 2023, 1120 (Dr. Stephen Nicolaidis).

26 HESA, *Evidence*, 9 May 2023, 1120 (Dr. Lorraine Greaves).

27 HESA, *Evidence*, 9 May 2023, 1105 (Dr. Jan Willem Cohen Tervaert).

28 HESA, *Evidence*, 11 May 2023, 1120 (Nancy Pratt); HESA, *Evidence*, 11 May 2023, 1105 (Julie Elliott).

- collecting reliable and comprehensive data on the risks and benefits of breast implants;[29] and
- proactively tracking the long-term safety of these devices.[30]

ELEMENTS OF A NATIONAL BREAST IMPLANT REGISTRY

Many witnesses put forward suggestions on how a breast implant registry could be optimally designed, discussing what organization(s) should be responsible for overseeing and managing the registry, how it should be funded and what data should be collected. The committee heard that best practices identified through research on existing breast implant registries in other countries could inform the development of a Canadian registry.[31] Dr. Peter Lennox, a professor and plastic surgeon, referenced certain key requirements, emerging from current research, for a successful breast implant registry:

- clear objectives;
- stable and long-term funding;
- financial and technical independence;
- a simple interface and data upload mechanism;
- mandatory data collection with an opt-out possibility for patients;
- concise data requirements; and
- clean data that can be utilized and reported easily.[32]

Dr. Lennox also highlighted data privacy and security as key elements for a database intended to contain patient information. According to Dr. Lennox, every patient in such a database would need a unique patient identifier to allow for patient tracking while

29 HESA, *Evidence*, 4 May 2023, 1105 (Dr. Peter Lennox).

30 HESA, *Evidence*, 4 May 2023, 1105 (Dr. Peter Lennox); HESA, *Evidence*, 4 May 2023, 1105 (Dr. Stephen Nicolaidis).

31 HESA, *Evidence*, 9 May 2023, 1130 (Dr. Steven Morris).

32 HESA, *Evidence*, 4 May 2023, 1205 (Dr. Peter Lennox).

retaining anonymity. Additionally, he noted that the data stored would need to be encrypted for security purposes.[33]

Witnesses discussed whether the registry should be mandatory for surgeons, for patients or for both. There was general support for having an "opt-out" style registry in which surgeons are mandated to input patient information unless the patient specifically requests to be excluded.[34] The committee heard that when participation is either voluntary for surgeons or "opt-in" for patients, lower uptake is expected, potentially jeopardizing the accuracy of the surveillance data gathered. Some witnesses felt that government oversight of a registry was needed, particularly to ensure compliance from private practices, where most breast implant surgeries are performed.[35]

One witness suggested the use of a steering committee[36] to guide the development of a registry, while another advocated for patient participation.[37] Several witnesses thought CIHI's Canadian Joint Replacement Registry (CJRR) could serve as a model for a breast implant registry.[38] However, government officials noted that the CJRR is not a safety-recall registry.[39] That is, although it collects information on hip and knee replacement surgeries performed in Canada, the CJRR is not used to notify patients of a recalled medical device or to share any other safety information with patients who have undergone such procedures.

Regarding the funding of a potential registry, it was suggested that the costs could be assumed by industry[40] or collected via a surcharge per implant paid by patients (for cosmetic procedures) or health insurance (for medically necessary procedures).[41]

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33 HESA, *Evidence*, 4 May 2023, 1145 (Dr. Peter Lennox).

34 HESA, *Evidence*, 4 May 2023, 1115 (Dr. Peter Lennox); HESA, *Evidence*, 9 May 2023, 1105 (Dr. Jan Willem Cohen Tervaert); HESA, *Evidence*, 11 May 2023, 1125 (Terri McGregor).

35 HESA, *Evidence*, 9 May 2023, 1155 (Dr. Lorraine Greaves); HESA, *Evidence*, 9 May 2023, 1130, 1200 (Dr. Steven Morris).

36 HESA, *Evidence*, 9 May 2023, 1130 (Dr. Steven Morris).

37 HESA, *Evidence*, 11 May 2023, 1115 (Terri McGregor).

38 HESA, *Evidence*, 4 May 2023, 1115 (Dr. Peter Lennox); HESA, *Evidence*, 9 May 2023, 1225 (Dr. Steven Morris).

39 HESA, *Evidence*, 25 April 2023, 1110 (Juliana Wu, Director, Acute and Ambulatory Care Information Services, Canadian Institute for Health Information).

40 HESA, *Evidence*, 4 May 2023, 1200 (Dr. Peter Lennox); HESA, *Evidence*, 4 May 2023, 1150 (Dr. Stephen Nicolaidis).

41 HESA, *Evidence*, 9 May 2023, 1200 (Dr. Jan Willem Cohen Tervaert).

In terms of data to include, certain witnesses proposed following best practices from other registries, as well as including patient-reported outcomes measures[42] and tracking other devices that are implanted at the same time as the breast implants, such as mesh or clips.[43]

The committee heard about several challenges associated with the implementation of a registry, including the protection of patient privacy, issues around health data sharing, the lack of established data flow from private clinics to federal data collection systems such as CIHI[44] and the inclusion of data on breast implants received outside Canada (through medical tourism or prior to immigration to Canada).[45] Representatives from CIHI stressed that a substantial amount of "foundational work" would be required to establish a registry, notably to determine the appropriate federal, provincial and territorial legislative framework, conduct an extensive privacy review and make complex legislative changes.[46] Databases currently housed at CIHI are not set up to manage an "opt-out" function, gather data from private clinics or notify patients in the event of recalls.

In general, witnesses did not feel that these challenges were insurmountable and noted that the desire for "perfection" should not impede the launching of a registry.[47] Dr. Steven Morris, President of the Canadian Association of Plastic Surgeons, suggested that "inertia" was the biggest obstacle to the implementation of a registry.[48]

PRE- AND POST-MARKET VIGILANCE

Certain witnesses, in addition to advocating for the creation of a registry, suggested that Health Canada make changes to its processes for pre- and post-market vigilance on breast implants. For example, some expressed concern with the procedure for reporting medical device incidents to Health Canada. According to Dr. Peter Lennox, plastic surgeons knew that the number of BIA-ALCL cases had been "far under-reported" to Health Canada

42 HESA, *Evidence*, 9 May 2023, 1200 (Dr. Jan Willem Cohen Tervaert).

43 HESA, *Evidence*, 11 May 2023, 1150 (Nancy Pratt).

44 HESA, *Evidence*, 25 April 2023, 1105 (David Boudreau); HESA, *Evidence*, 25 April 2023, 1135 (Juliana Wu).

45 HESA, *Evidence*, 11 May 2023, 1120 (Nancy Pratt); HESA, *Evidence*, 11 May 2023, 1200 (Terri McGregor); HESA, *Evidence*, 11 May 2023, 1200 (Julie Elliott).

46 HESA, *Evidence*, 25 April 2023, 1110 (Juliana Wu); Canadian Institute for Health Information, *Response to House of Commons Canada - Standing Committee on Health in the context of the study of oversight of medical devices (breast implants)*, May 2023.

47 HESA, *Evidence*, 9 May 2023, 1125 (Dr. Lorraine Greaves).

48 HESA, *Evidence*, 9 May 2023, 1225 (Dr. Steven Morris).

in 2017.[49] He elaborated that the process for reporting incidents constitutes a barrier, since it is challenging for private clinics to navigate. The reporting of medical device incidents is mandatory for hospitals and manufacturers;[50] some witnesses called for mandatory incident reporting to be extended to private practices as well.[51]

In addition, some witnesses discussed the requirements for Health Canada's pre-market review and post-market surveillance of breast implants. Dr. Jan Willem Cohen Tervaert noted that the licensing process for medical devices requires less stringent scientific evidence of safety and effectiveness when contrasted with the process for medications.[52] Further, the committee heard that certain manufacturers abandoned their post-market, long-term safety studies of their breast implants.[53]

Some patient advocates recommended that the sale of breast implants be paused or limited pending improvements in the oversight of these devices.[54]

Furthermore, Dr. Lorraine Greaves, Chair of Health Canada's SAC-HPW, said that the SAC-HPW has recommended both a retrospective case study of the regulatory gaps pertaining to these devices and the creation of a fund to cover the cost of breast implant injuries.[55]

CONSUMER INFORMATION AND INFORMED CONSENT

A recurrent theme throughout the testimony was that women frequently lack comprehensive information about potential risks prior to implantation. For example, patient advocate Julie Elliott told the committee that informed consent discussions often centre around potential complications from the surgery itself, rather than adverse effects such as BIA-ALCL, autoimmune disease or breast implant illness.[56] Additionally, she noted that Health Canada provides inadequate information for consumers on its

49 HESA, *Evidence*, 4 May 2023, 1130 (Dr. Peter Lennox).

50 HESA, *Evidence*, 25 April 2023, 1105 (David Boudreau).

51 HESA, *Evidence*, 9 May 2023, 1125 (Dr. Lorraine Greaves); HESA, *Evidence*, 11 May 2023, 1115 (Terri McGregor).

52 HESA, *Evidence*, 9 May 2023, 1235 (Dr. Jan Willem Cohen Tervaert).

53 HESA, *Evidence*, 11 May 2023, 1240 (Julie Elliott).

54 HESA, *Evidence*, 11 May 2023, 1115 (Terri McGregor); HESA, *Evidence*, 11 May 2023, 1120 (Nancy Pratt).

55 HESA, *Evidence*, 9 May 2023, 1140, 1145 (Dr. Lorraine Greaves).

56 HESA, *Evidence*, 11 May 2023, 1230 (Julie Elliott).

website regarding the safety of breast implants.[57] The committee also heard that patients are not sufficiently informed of the need for periodic medical imaging of the implant (e.g., through magnetic resonance imaging), which is recommend by the United States Food and Drug Administration for the monitoring of breast implants.[58] Further, Dr. Lorraine Greaves said that women should have more information, in particular, "robust information about consumer experiences; reasons and motivations for seeking implants; alternatives to implants; lifespan of devices; and relevant qualitative research."[59]

Lack of informed consent is also a theme reflected in the briefs. Some women indicated that, had they been properly advised of the risks, they would not have chosen to have breast implants. Others felt that they had been pressured into receiving implants or had lacked sufficient information about alternatives. When directly asked whether he would be comfortable recommending breast implants to his own daughter, Dr. Jan Willem Cohen Tervaert replied: "Never."[60] Adding to this discussion, Dr. Lorraine Greaves told the committee: "I certainly wouldn't recommend this device to anyone I know. The best breast implant is probably one that is avoided."[61]

Certain witnesses urged Health Canada to improve its messaging on the risks of breast implants, as well as to make efforts to enhance communication between plastic surgeons and potential breast implant recipients. For example, patient advocates recommended that Health Canada include photographs showing adverse effects of breast implants on its website.[62] Appendix A includes examples of photographs that show breast implant complications and that were submitted to the committee by Nancy Pratt. Some witnesses recommended the development of a standardized informed-consent form or checklist.[63]

57 HESA, *Evidence*, 11 May 2023, 1210 (Julie Elliott).

58 HESA, *Evidence*, 11 May 2023, 1200 (Terri McGregor); HESA, *Evidence*, 11 May 2023, 1210 (Julie Elliott); United States Food and Drug Administration, *Breast Implants - Certain Labeling Recommendations to Improve Patient Communication: Guidance for Industry and Food and Drug Administration Staff*, September 2020.

59 HESA, *Evidence*, 9 May 2023, 1120 (Dr. Lorraine Greaves).

60 HESA, *Evidence*, 9 May 2023, 1150 (Dr. Jan Willem Cohen Tervaert).

61 HESA, *Evidence*, 9 May 2023, 1255 (Dr. Lorraine Greaves).

62 HESA, *Evidence*, 11 May 2023, 1115 (Terri McGregor); HESA, *Evidence*, 11 May 2023, 1140 (Nancy Pratt).

63 HESA, *Evidence*, 4 May 2023, 1150 (Dr. Stephen Nicolaidis); HESA, *Evidence*, 11 May 2023, 1250 (Julie Elliott).

THE NEED FOR RESEARCH ON BREAST IMPLANTS

Several witnesses highlighted a need for more research on breast implants, including both qualitative and quantitative research. Dr. Lorraine Greaves suggested that the Canadian Institutes of Health Research be encouraged to use data from the breast implant registry, once it has been established, to inform such research.[64] Patient advocate Nancy Pratt told the committee that directed public funding was needed to support independent research: "This is not a role for the industry, given its history and its obvious conflict of interest."[65] Further, Terri McGregor suggested that research be conducted to estimate the burden placed on public health care systems by the adverse effects of breast implants.[66]

GENDER EQUITY AND BODY IMAGE

For some witnesses, the inadequate oversight of breast implants represents a gender equity issue. Patient advocates recounted how the health care system frequently ignores women's experiences with breast implants. In Terri McGregor's view, this dismissal is an example of "a patriarchal hierarchy of medicine gaslighting female patients."[67] Dismissal of women's concerns was also highlighted in many of the briefs submitted by patients.

According to Dr. Lorraine Greaves, systemic bias against women is an ongoing issue in health research and treatment in general. In her words, "[w]omen's health has a long history of neglect."[68] Dr. Greaves also noted that Health Canada has not yet mandated the inclusion of sex- or gender-related data in submissions by industry for medical devices or drugs.[69]

The pressures women face to conform to a certain body image was discussed as one of the motivating factors for breast implant surgery. Dr. Greaves recommended that further research be conducted to shed light on patients' motivations for seeking breast

64 HESA, *Evidence*, 9 May 2023, 1120 (Dr. Lorraine Greaves).

65 HESA, *Evidence*, 11 May 2023, 1120 (Nancy Pratt).

66 HESA, *Evidence*, 11 May 2023, 1115 (Terri McGregor).

67 HESA, *Evidence*, 11 May 2023, 1255 (Terri McGregor).

68 HESA, *Evidence*, 9 May 2023, 1115 (Dr. Lorraine Greaves).

69 HESA, *Evidence*, 9 May 2023, 1125 (Dr. Lorraine Greaves); Government of Canada, *Scientific Advisory Committee on Health Products for Women (SAC-HPW): Summary of findings and advice, February 1st, 2022 virtual meeting*.

implants and that the results of this research be used to inform consumers.[70] She told the committee that Health Canada has a responsibility to educate consumers on this topic and to "raise questions about the usage of implants."[71]

CONCLUSION AND RECOMMENDATIONS

It is clear from the evidence received during this study that more must be done to strengthen the oversight of breast implants in Canada. Repeated calls for action have gone unheeded for decades; action is long overdue. As Dr. Steven Morris told the committee:

> It's said that the best time to plant a tree is 30 years ago, and the second-best time to plant a tree is today. It's the same with this registry. Today is the best time to start moving forward with this issue.[72]

Taking action to protect the health and safety of those who have received or are considering getting breast implants is critical. Progress must be made towards, notably, implementing a national breast implant registry designed in line with international best practices; ensuring that Health Canada sufficiently informs consumers of the risks of breast implants; improving pre- and post-market vigilance on breast implants; funding research on breast implants; and addressing gender inequities in health research. Therefore, the committee recommends:

Recommendation 1

That, as soon as possible, the Government of Canada establish a national breast implant registry that would allow:

- **breast-implant recipients to receive information and be contacted in the event of a recall;**
- **reliable and comprehensive data on the risks and benefits of breast implants to be collected; and**
- **the long-term safety of these devices to be proactively tracked.**

70 HESA, *Evidence*, 9 May 2023, 1255 (Dr. Lorraine Greaves).

71 HESA, *Evidence*, 9 May 2023, 1205 (Dr. Lorraine Greaves).

72 HESA, *Evidence*, 9 May 2023, 1225 (Dr. Steven Morris).

Recommendation 2

That the Government of Canada quickly establish a committee made up of officials from Health Canada, experts and patient representatives, and work with provinces and territories to achieve this goal.

Recommendation 3

That the Government of Canada ensure that the national breast implant registry is implemented via a mandatory, uniform informed-consent form that has a clear checklist, that is signed by the surgeon and patient, and that offers the patient the possibility of opting out of the registry.

Recommendation 4

That the Government of Canada ensure that the national breast implant registry has stable and long-term funding, that the registry uses a cost-recovery model, and that the costs are funded by breast implant manufacturers.

Recommendation 5

That the Government of Canada ensure that the national breast implant registry includes patient-reported outcome measures and tracks other devices implanted at the same time as the breast implants, such as mesh or clips.

Recommendation 6

That Health Canada continue to work with the Canadian Institute for Health Information and provinces and territories to develop and implement data standards.

Recommendation 7

That the Government of Canada facilitate the process of reporting adverse events to Health Canada and extend the obligation to private practices.

Recommendation 8

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 9

That Health Canada recognize breast implant illness.

Recommendation 10

That the Government of Canada fund research on breast implants, including, but not limited to, long-term health effects.

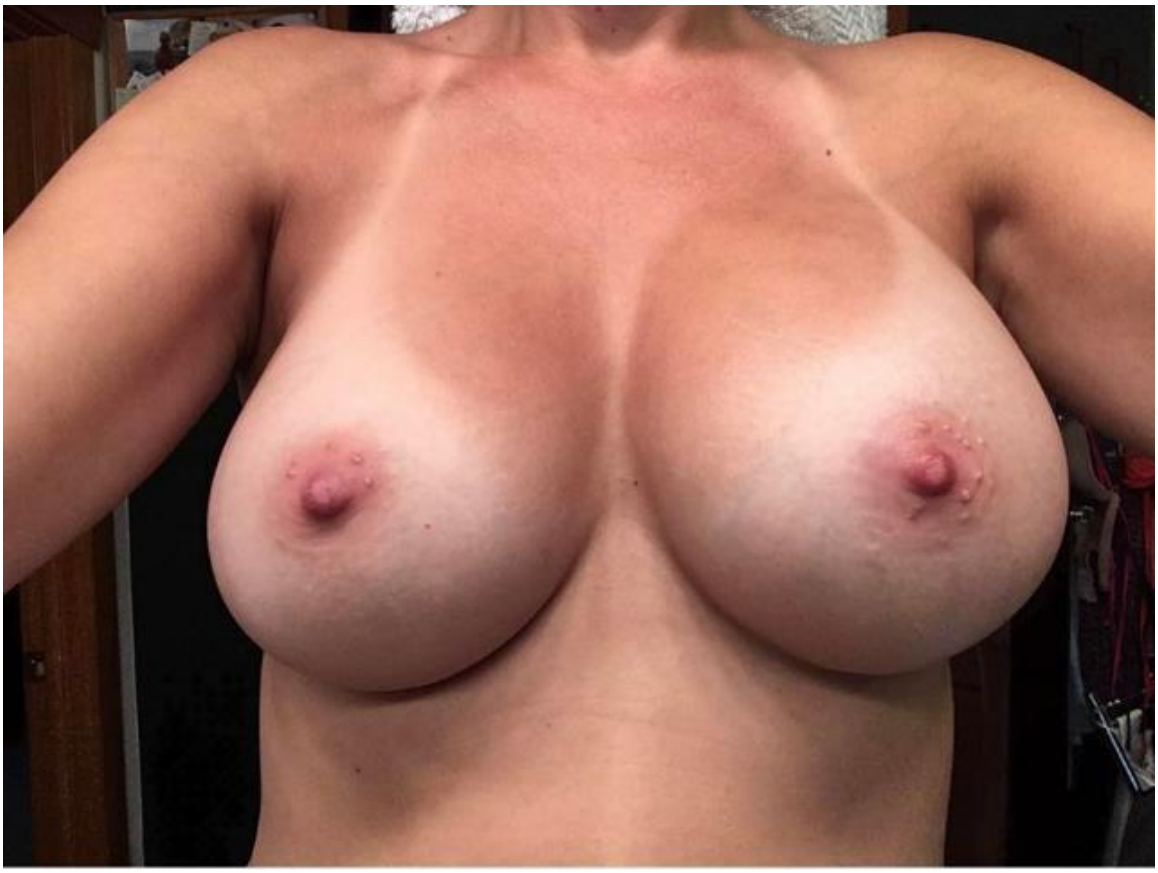
The committee thanks all the witnesses who participated in this study and who submitted written briefs, particularly those who shared their personal stories about breast implant complications. Their expertise and dedication to protecting the health and safety of breast implant recipients are greatly appreciated.

APPENDIX A: PHOTOGRAPHS OF BREAST IMPLANT COMPLICATIONS

WARNING: This appendix contains images with partial nudity and graphic medical content.

Patient advocates have recommended that Health Canada include photographs showing the complications of breast implants on its website to increase awareness of potential adverse effects and improve informed consent. Figures A1 through A10 provide a selection of such photographs.

Figure A1—Swollen Left Breast in a Patient with Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)



Note: The patient's left breast is swollen. One of the main symptoms of BIA-ALCL is persistent swelling around the breast implant.[1]

Source: Photo courtesy of the Breast Implant Failure & Illness Society – Canada, submitted to the committee by Nancy Pratt.

1 United States Food and Drug Administration, *Questions and Answers about Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)*.

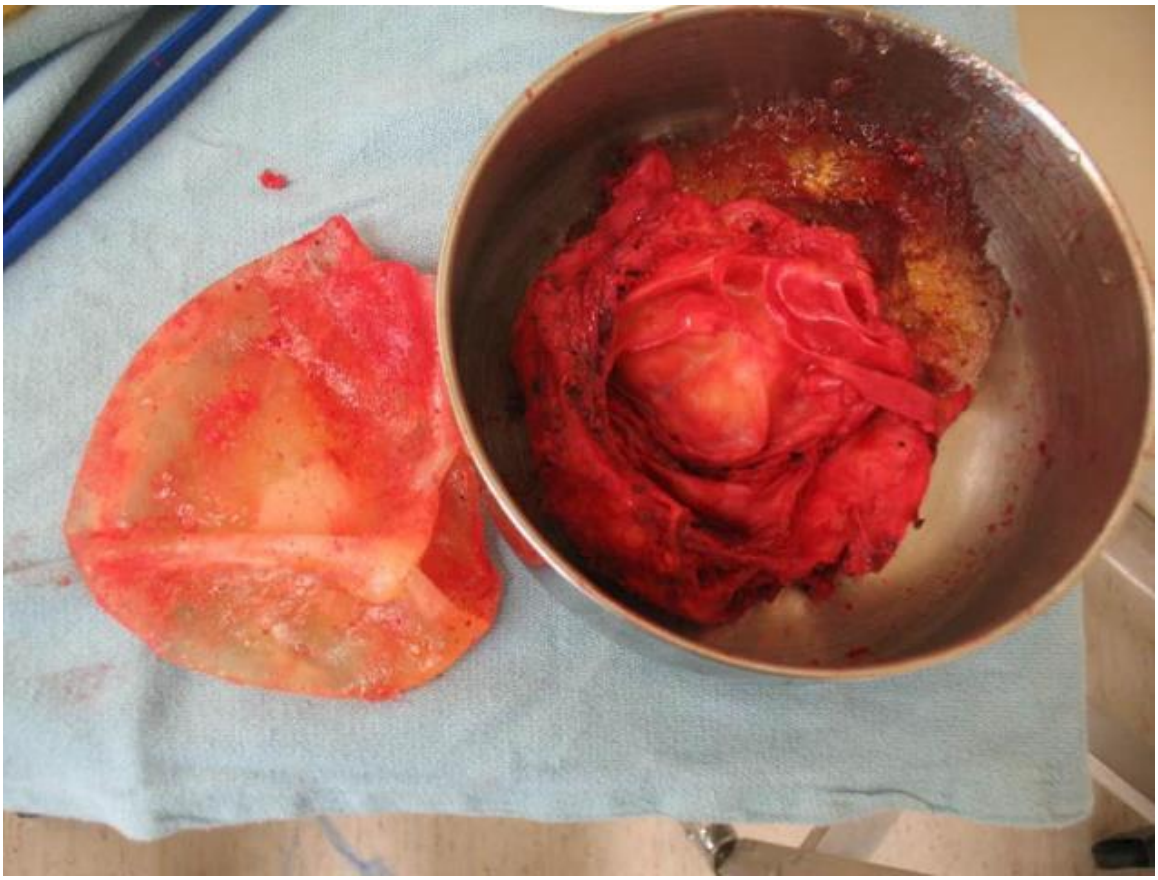
Figure A2—Syringes Filled with Seroma from a Patient Diagnosed with BIA-ALCL

Note: Patients with BIA-ALCL often have an accumulation of fluid (seroma) around the breast implant.[2]

Source: Photo courtesy of the Breast Implant Failure & Illness Society – Canada, submitted to the committee by Nancy Pratt.

2 United States Food and Drug Administration, *Questions and Answers about Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)*.

Figure A3—Mass Found in Capsule of Patient with Stage 4 BIA-ALCL

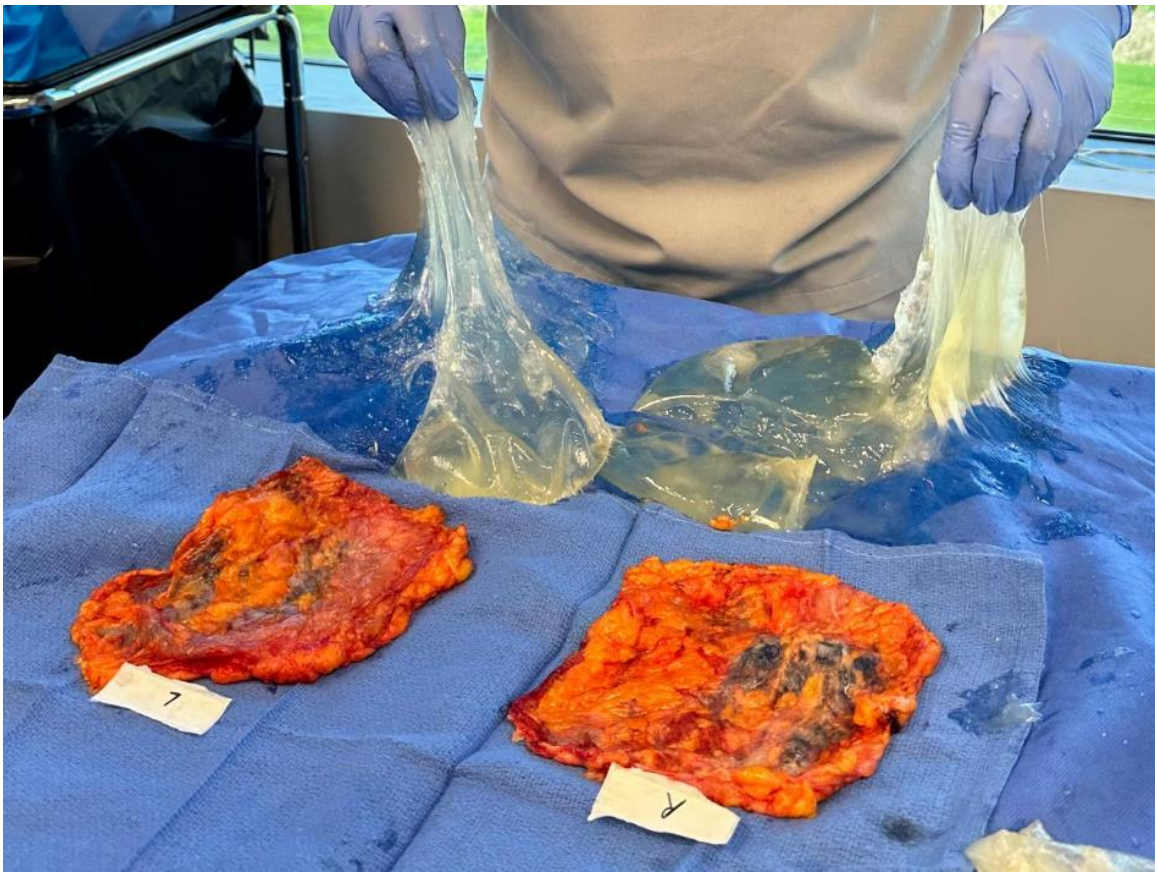


Note: Lumps around the breast or armpit can be a sign of BIA-ALCL.[3]

Source: Photo courtesy of the Breast Implant Failure & Illness Society – Canada, submitted to the committee by Nancy Pratt.

3 United States Food and Drug Administration, *Questions and Answers about Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)*.

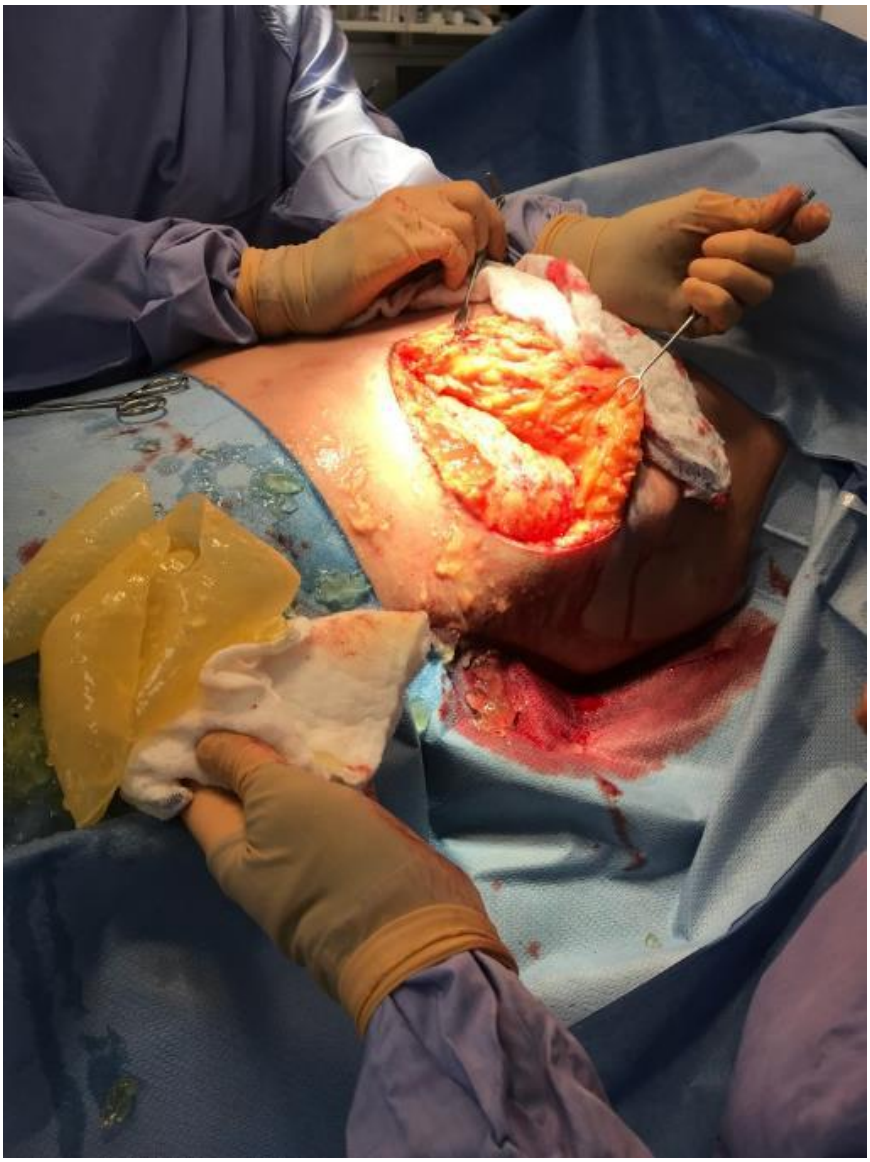
Figure A4—Ruptured Cohesive Silicone Gel ("Gummy Bear") Breast Implants



Note: Rupture is a possible complication of both saline and silicone implants.

Source: Photo courtesy of Dr. Aditya Sood, submitted to the committee by Nancy Pratt.

Figure A5—Rupture of Poly Implant Prothèse (PIP) Breast Implant

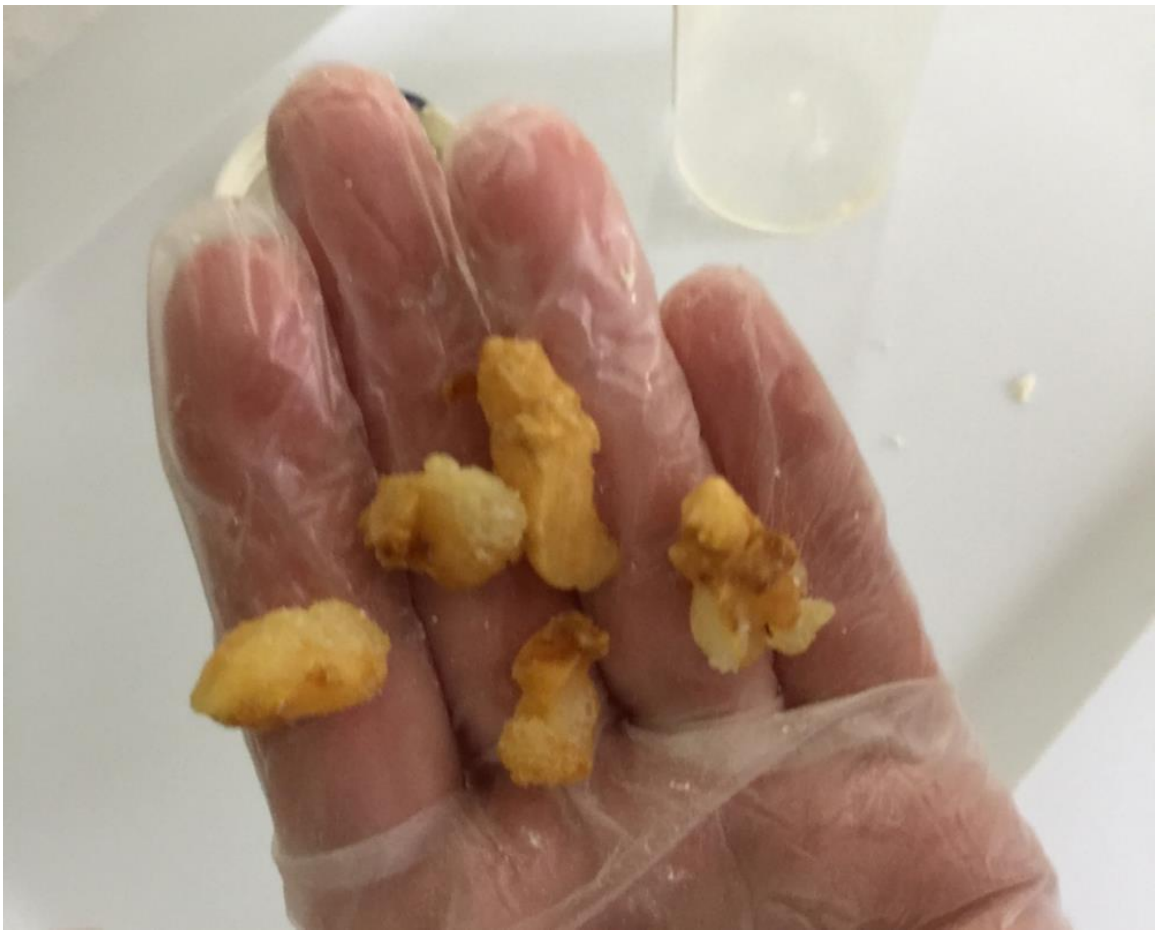


Note: Silicone implants manufactured by the French company Poly Implant Prothèse (PIP) were removed from the market after health authorities in France discovered they contained industrial-grade rather than medical-grade silicone and were more prone to rupture.[4] Although PIP implants were never distributed in Canada, patients in Canada may have received them while abroad.

Source: Photo courtesy of Dr. Stephen Nicolaidis, submitted to the committee by Nancy Pratt.

4 France 24, *French PIP breast implants: an ongoing global health scandal*, 29 September 2018.

Figure A6—Silicone Granulomas

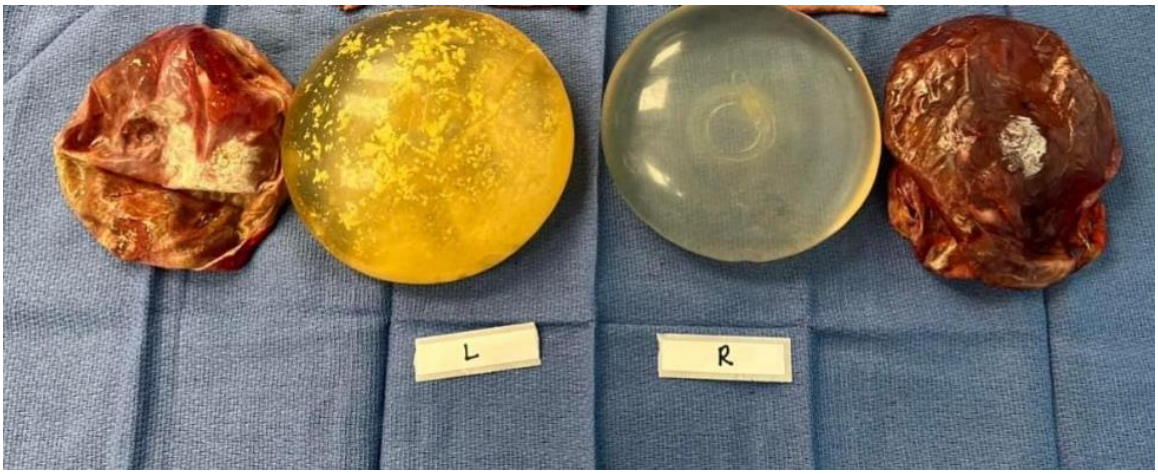


Note: Silicone granuloma formation may occur following extracapsular rupture of a breast implant (i.e., when silicone escapes beyond the capsule around the implant). There have been reports of silicone granulomas found in numerous sites throughout patients' bodies.[5]

Source: Photo courtesy of the Breast Implant Failure & Illness Society – Canada, submitted to the committee by Nancy Pratt.

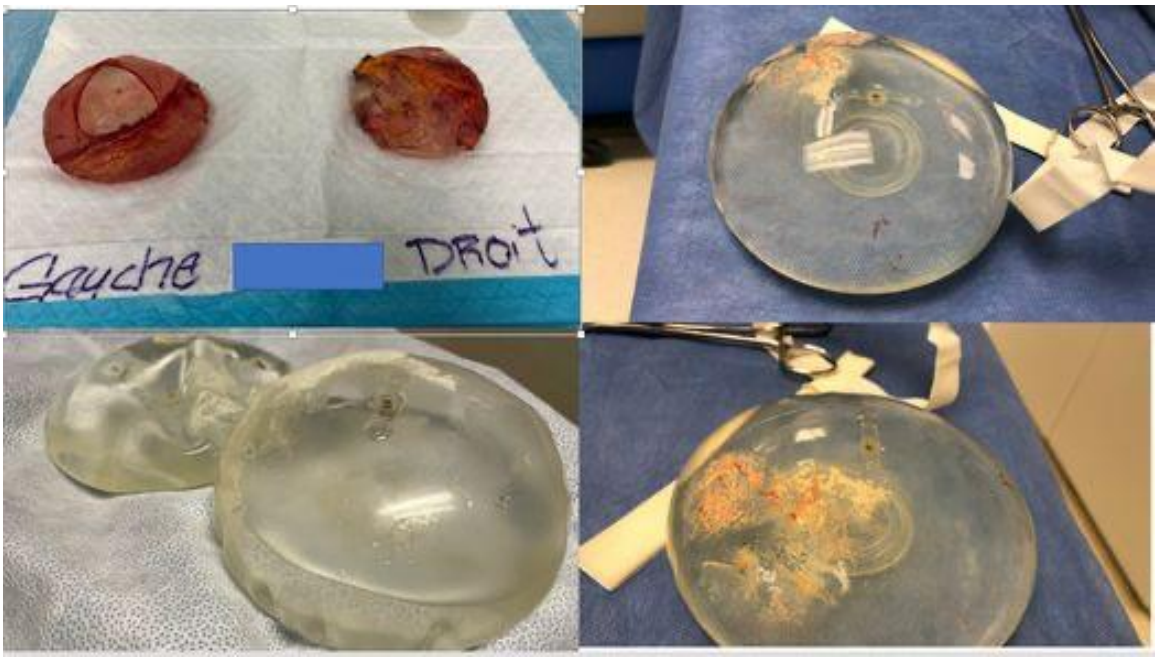
5 Hanad Ahmed et al., "Chest Wall Silicone Granuloma Following Ruptured Silicone Breast Implant Causes Giant Chest Wall Abscess and Osteomyelitis: The First Report," *European Journal of Breast Health*, Vol. 17, No. 4, October 2021.

Figure A7—Debris in a 23-Year-Old Saline Breast Implant



Source: Photo courtesy of Dr. Aditya Sood, submitted to the committee by Nancy Pratt.

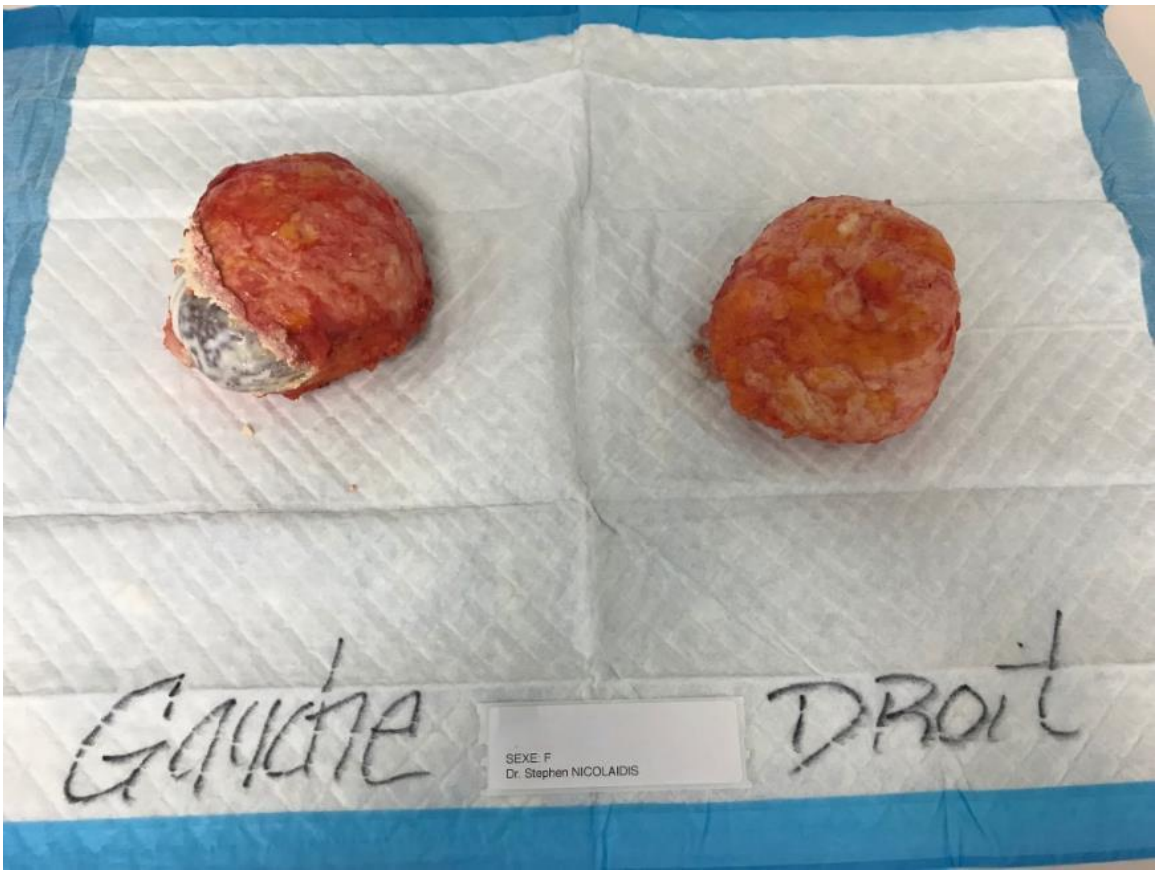
Figure A8—Smooth Saline Implants Recalled Because of Valve Issue



Note: The top left image shows implants in scar capsules. The bottom left image shows a saline leak. The photos on the right show discolouration with possible contamination of the implant.

Source: Photo courtesy of the Breast Implant Failure & Illness Society – Canada, submitted to the committee by Nancy Pratt.

Figure A9—Grade IV Capsular Contracture



Note: Capsular contracture refers to the tightening or hardening of scar tissue around the implant. The severity of capsular contracture is graded on a scale from I to IV, with I representing the least severe (asymptomatic) and IV representing the most severe (hard, misshapen and/or painful breasts).[6]

Source: Photo courtesy of Dr. Stephen Nicolaidis, submitted to the committee by Nancy Pratt.

6 Kevin Tehrani, "What is capsular contracture and how can it be treated?," *American Society of Plastic Surgeons*, 12 June 2018.

Figure A10—Heavily Calcified 30-Year-Old Breast Implants

Note: Calcium deposits can form on the breast implant capsule. Calcification can interfere with breast cancer screening.[7]

Source: Photo courtesy of Dr. Aditya Sood, submitted to the committee by Nancy Pratt.

7 United States Food and Drug Administration, *Risks and Complications of Breast Implants*.

APPENDIX B:
LIST OF WITNESSES

The following table lists the witnesses who appeared before the committee at its meetings related to this report. Transcripts of all public meetings related to this report are available on the committee's webpage for this study.

Organizations and Individuals	Date	Meeting
Canada Health Infoway	2023/04/25	63
Abigail Carter-Langford, Chief Privacy and Security Officer		
Canadian Institute for Health Information	2023/04/25	63
Juliana Wu, Director Acute and Ambulatory Care Information Services		
Department of Health	2023/04/25	63
David Boudreau, Director General Medical Devices Directorate, Health Products and Food Branch		
As an individual	2023/05/04	66
Dr. Peter Lennox, Clinical Professor Division of Plastic Surgery, The University of British Columbia		
Dr. Stephen Nicolaidis, Assistant Professor of Surgery Université de Montréal		
As an individual	2023/05/09	67
Dr. Jan Willem Cohen Tervaert, Professor of Medicine University of Alberta		
Canadian Society of Plastic Surgeons	2023/05/09	67
Dr. Steven Morris, President		
Scientific Advisory Committee on Health Products for Women	2023/05/09	67
Dr. Lorraine Greaves, Chair		
Breast Implant Failure and Illness Society Canada	2023/05/11	68
Nancy Pratt, Patient Advocate		

Organizations and Individuals	Date	Meeting
Breast Implant Safety Alliance Julie Elliott, Patient Advocate Terri McGregor, Patient Advocate	2023/05/11	68

APPENDIX C:
LIST OF BRIEFS

The following is an alphabetical list of organizations and individuals who submitted briefs to the committee related to this report. For more information, please consult the committee's webpage for this study.

Anonymous Author

Bellemare, Julie

Bizier, Cynthia

Bouchard, Ingrid

Breast Implant Safety Alliance

Canadian Cancer Society

Couture, Chantal

Criss, Dawn

d'Anjou, Olivette

Denis, Liliane

Dupuis, Stéphanie

Ferland, Danielle

Fontaine, Marie-Josée

Frend, Sheri

Gane, Diane

Gaudette, Marie-Josée

Gendron, Jacqueline

GS1 Canada

Haché, Jénifer

Houde, Lindsay

Hupé, Suzanne Michèle

Johnston, Laura

Lachambre, Lyne

Landry, Stéfanie

Lavoie, Isabelle

Lévesque, Dominique

Marchand, Anouk

Piette, Lucie

Pitre, Hélène

Prado, Carolina

Proulx-Cholette, Emmanuelle

Richer, Danielle

Rousseau, Geneviève

Therrien, Anne

Thompson, Patricia

Tremblay, Annie

Tremblay, Isabelle

Turcot, Terry

Turgeon, Marie-Josée

Vaillant, Nathalie

REQUEST FOR GOVERNMENT RESPONSE

Pursuant to Standing Order 109, the committee requests that the government table a comprehensive response to this report.

A copy of the relevant *Minutes of Proceedings* (Meetings Nos. 63, 66, 67, 68, 73, 80, 81 and 89) is tabled.

Respectfully submitted,

Sean Casey
Chair