## Breast implant advisory panel: more study on silicone leakage

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Two companies that manufacture silicone-gel breast implants have not satisfied a Health Canada expert advisory panel about the potential health effects of exposure to low-molecular-weight silicones if the implants leak, or about long-term safety, the panel says in a report released January 12.

The manufacturers – Mentor Corporation and Inamed Corporation – "must demonstrate that migrated silicone provides acceptable risks of hypersensitivity and autoimmunity by a critical review of company and literature data and, if necessary, by undertaking studies in animal models," the report says.

Most tests performed to demonstrate that the implants do not "bleed" excessive amounts of gel were not in vivo, the panel reported. Members asked for further animal models specifically looking at the issue of leakage, or gel bleed, and want more long-term safety data.

"The data is [sic] sufficient to establish how the devices perform in vivo," the report says. "However they do not address all aspects of long-term safety. Annual reports must be submitted that update on ongoing studies, particularly up to 10 year follow-up..."

An annual report that is readily accessible to the public should also include feedback from health care professionals, compiled either by the manufacturers or by Health Canada, the panel recommends.

Members were asked to consider several scientific and technical questions in 3 areas: preclinical data, clinical data and labelling to accompany the devices should they be returned to the market. The panel was not asked to provide an overall opinion as to whether the devices should be sold in Canada.

That mandate is the biggest problem with the report as a whole, says Anne Rochon Ford, coordinator of Women and Health Protection. The national organization monitors decisions by Health Canada's Health Products and Food Branch and testified at public hearings during the panel process.

"The mandate was narrow," Ford told *CMAJ*. "The bigger overriding question – should these be approved – was not asked. That was not part of the deal. That was a conscious decision on the part of Health Canada."

The report does not reflect the "strong differences of opinion" expressed during the public hearings, she says. For instance, the panel is making no distinction between women seeking breast augmentation, and those who want reconstruction after mastectomies.

"We're not talking here about the bigger question of how far along our support of distorted body images has gotten, that we have a federal government department considering public dollars going to a product and a procedure that essentially institutionalizes a distorted body image," Ford says.

"The fact that none of that was part of the questioning, none of that was heard from the hearings – and it was loudly spoken by some of us – was a real shortcoming in the process."

In recommendations that went beyond its mandate, the panel did advise Health Canada to establish a national registry of breast implant patients, and to develop a "decision aid" – material that would help women balance the harms and benefits of choosing to have a breast implant. Ford praised those recommendations.

"In particular, the decision aid will need to adequately reflect the information that will be part of labelling, including quality of life, the lifetime of these devices and issues related to body image and mental health," the report says.

The national registry would provide more information about the safety and efficacy of the prostheses and supply a larger potential patient pool for conducting research, the report notes.

There is no evidence of an increase in autoimmune diseases in women with implants in the short term, the report says. Many women who have had breast implants and then had them removed have made that link themselves, and some of them testified about their illnesses at a public comment session that Health Canada held last fall. A national registry and longer-term studies would allow researchers to continue to investigate that issue, the report says.

Inamed Corporation could not be reached for comment by press time, but a spokesman for Mentor Corporation issued the following statement about the panel report: "We believe in the scientific evidence supporting our products and look forward to Mentor's Memory Gel breast implants becoming an important additional option for women seeking breast reconstruction or augmentation in Canada."

Health Canada regulators will consider this report in conjunction with public comment, along with data the manufacturers submitted as part of their applications to allow their products back on the Canadian market. They hope to make a decision within "a matter of months."

"Health Canada as part of their regular review process will decide whether or not to grant market approval status," says Dr. Supriya Sharma, associate director general of Health Canada's Therapeutic Products Directorate.

She would not say what weight those recommendations or the public input would have, however. Sharma did note that the recommendation for additional studies with regard to silicone bleed may affect the timing of any regulatory decision.

Breast implants were withdrawn in January 1992 after safety concerns and amidst burgeoning court cases. At least 4 class-action lawsuits involving the

safety of an earlier generation of breast implants manufactured by Dow-Corning before 1992 name Health Canada, accusing it of failing in its duty to ensure the devices were safe and effective before allowing them on the market.

Health Canada solicited affidavits on its behalf from 4 members of the panel, including its chair, George Wells, in one of the lawsuits. Three of the panel members also declared conflicts of interest involving financial ties to one or more of the manufacturers before the proceedings began – both of these issues "hugely problematic" for Women and Health Protection.

"That too got swept under the carpet, despite the Standing Committee on Health's major concerns about it," says Ford, who believes the report's release during the election campaign, when the Standing Committee is not sitting, may mean it will not attract the attention she thinks it deserves.

Other recommendations in the report include:

- These specialized devices require additional education for surgeons, since proper use is critical. The panel "very strongly recommends" that Health Canada provide these prostheses only to certified Royal College plastic surgeons who have been specifically trained in implanting them.
- Patient information should acknowledge that the implant is not a lifetime device and will likely need to be replaced, necessitating subsequent surgery.
- Current labelling does not adequately present all data and should be available to patients to consider before surgery, as printed material and on a Web site. Contraindications should include clinical depression, eating disorders, and desire to breast feed babies.
- Patient and physician information should include an advisory that multiple surgical procedures on the breast may cause irreversible changes to the breast itself, and physicians should be advised that "strong consideration should be given to implant removal" in the case of multiple surgeries.
- Physicians should be told that breast implants are not indicated for patients presenting "with body dysmorphia or any other psychosis."
- Patients presenting with depression and/or an eating disorder should be referred for treatment before considering breast augmentation surgery, and labelling should caution such patients to postpone the decision for breast augmentation until their depression and/or eating disorder is resolved.

—Laura Eggertson, *CMAJ*

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