

MPs call for removal of Health Canada's breast-implant panel members

Opposition MPs are calling on Health Canada to remove members of an expert advisory panel on breast implants, or to suspend the panel's work, because at least 3 members have ties to manufacturers of the medical devices.

"Why would we say it was acceptable for people who had been paid by these companies to actually vote on whether they're licensed?" Jean Crowder, the NDP health critic, asked the Parliamentary Health Committee Oct. 4.

Crowder says she is worried the public will perceive the panel's recommendations as being influenced by the 3 members who have either worked for, or had their travel expenses paid by, 2 corporations whose licensing applications they are now assessing.

Health Canada has charged the 13-member panel with evaluating the safety and efficacy data submitted by Inamed Corporation and Mentor Corporation in their bid to sell silicone gel breast implants in Canada. The panel met Sept. 29 and 30.

Health Canada is opposing the women's attempt to get their lawsuit certified as a class action.

Crowder's motion, which Bloc MP Nicole Demers and some members of the Liberal and Conservative parties on the committee supported, initially asked that Harold J. Brandon, Michael A. Brook and Mitchell Brown be removed from the panel. That motion was subsequently amended to request that Health Minister Ujjal Dosanjh attend the committee at his earliest opportunity to explain the panel's make-up. That motion was approved.

Meanwhile, *CMAJ* has learned that the 3 panel members not only had ties to industry, but also, along with panel

Chair George Wells, recently submitted affidavits on behalf of Health Canada in a lawsuit against the regulator.

In a cryptic Web site posting on Sept. 29, Health Canada acknowledged that 4 panel members had filed affidavits in a lawsuit, but didn't elaborate on what case the affidavits concerned. Health Canada has since removed the posting.

In fact, women who received an earlier generation of silicone gel implants manufactured by Dow-Corning filed the lawsuit, which alleges Health Canada failed in its duty by not ensuring the devices were safe and effective.

The 4 men all made their depositions after being named to the expert panel.

In his Sept. 26 affidavit, Brook stated that there was no way to determine the origin of silicone in someone's body.

In his Sept. 23 affidavit, Wells attested that even if silicone leaked from the implants, the "alleged diseases, signs or symptoms of each plaintiff in this case do not generalize to all persons with Dow-Corning silicone breast implants."

The lawsuit, which is in Ontario Superior Court, is 1 of 4 naming Health Canada. One of those actions has been filed in Federal Court; the others are in British Columbia and Saskatchewan. A judge may decide to amalgamate all of the cases.

Lawyers with the justice department, who are defending Health Canada, are opposing the women's attempt to get their lawsuit certified as a class action. Certification would allow their claim to be generalized to all women with Dow-Corning implants.

When asked by *CMAJ* about whether he perceived his involvement on behalf of the federal government in the class action suit posed a conflict of interest for his panel membership, Wells would not discuss the case. He did say however, that the expert community in Canada is relatively small, and those with experience



Pierre Blais

This ruptured silicone gel Dow-Corning implant from the late 1960s was removed after 12 years.

and expertise are in high demand. "We're dealing with different products than we were dealing with in 1992," he added.

Dr. Siddika Mithani, associate director general of Health Canada's Therapeutic Products Directorate, said Wells and the other panel members who testified in the court case did not have a conflict of interest because different companies are involved.

"We need to focus on what we are doing today — which is to focus on the licensing applications before us, rather than on the past," she said. "We are talking about 2 different issues here and device applications that are very different."

The panel members are all experts in this area and "it has been extremely valuable to get their input," she added.

Crowder and other MPs don't see it this way. "I absolutely have a concern about that," Crowther said, referring to the 4 panel members' involvement in the lawsuit. "I want them removed."

"The issue isn't [about] impugning the integrity of these people involved, but surely there must be other experts in North America that have not been involved in either the legal part of it or involved in being in the employ of these companies," she said. — Laura Eggertson, with files from Sally Murray, *CMAJ*

DOI:10.1503/cmaj.051329