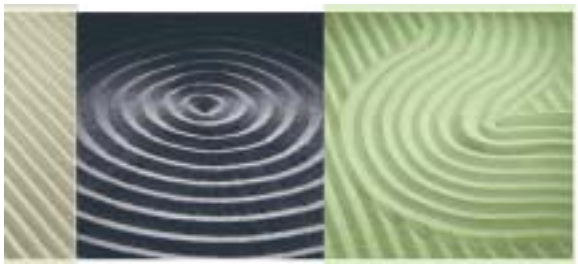

MILLER THOMSON LLP

Barristers & Solicitors, Patent & Trade-Mark Agents

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VOLUNTARY PROBLEM REPORTING FOR MEDICAL DEVICES

Catharine Schiller
Toronto
Tel. 416.595.8638
cschiller@millerthomson.ca

Kathryn Frelick
Toronto
Tel. 416.595.2979
kfrelick@millerthomson.ca

Medical device problem reporting is an essential step in ensuring the safety and efficacy of devices for both the patients and staff who use medical equipment. Although manufacturers and importers have mandatory requirements to report medical device problems under the *Medical Devices Regulations* of the *Canada Food and Drugs Act*, voluntary reports filed by users such as health care facilities can often identify unique and crucial issues. Health care professionals have an advantage in their ability to evaluate the implications of a particular device problem given their understanding of the procedures and conditions under which the problem occurred.

Health Canada encourages health care facilities to report any issues that have been discovered during device examination, testing or use and that relate to the safety, effectiveness or quality of any medical device. Such problems can include deficiencies in the design of the device, faulty manufacturing or quality assurance issues, and inadequacy and errors in labeling. The problem can reveal itself during actual use of the medical device or the user may develop concerns about its safety or ability to perform as claimed before the device is even used.

WHAT IS A VOLUNTARY PROBLEM REPORT?

A voluntary problem report is any description of a complaint or incident involving a medical device that is forwarded to the Health Products and Food Branch Inspectorate ("Inspectorate") of Health Canada and made at the discretion of the reporter. Health care professionals are urged to make voluntary reports for all types of device problems to both the manufacturer and the Inspectorate. Failing to notify these two groups could place patients at risk in other facilities that remain unaware of the problem.

Although all reported incidents are entered into a national incident database by the Inspectorate, investigation of voluntary reports is performed on a risk management basis with higher risk situations given higher priority. After a report has been made, a Health Canada inspector may visit the health care facility to examine the medical device and speak with the users, if required, and then follow-up with the manufacturer or importer as needed.

It is important to remember that reporting problems can prevent similar situations from recurring and can lead to product improvements in terms of design, directions, or even complete recalls of a particular version of the product. The information could also lead to the issuance of either a warning to other facilities who use the product or a Medical Device Alert.

I M P L I C A T I O N S

Health care facilities have a responsibility to ensure the safety of the medical equipment that they use and should, if questioned, be able to demonstrate that they have performed their due diligence in this area. Where concerns about the safety or quality of the medical devices used in a health care facility are raised, these should be properly investigated through an internal investigation and/or an external review. As noted above, due diligence may require reporting the problem to the manufacturer of the device as well as engaging the expertise of Health Canada by filing a voluntary medical device problem report.

If an incident involving a medical device has occurred at your facility, it is important to ensure that appropriate possession and control of the device is maintained and that incidents and any investigative steps that are undertaken are well-documented. Since the documentation that is created through a review may be producible in court proceedings, it is important that factual and concise language be used. We recommend that, for high-risk incidents, you contact legal counsel.

C O N T A C T I N G T H E I N S P E C T O R A T E

If you would like to speak with a Medical Device Inspector in your region about the details of an incident that has occurred in your facility, the Inspectorate Hotline number is 1-800-267-9675. The Medical Devices Problem Reporting Form is available online at: http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/man_vol_pro_rep_md_entire_e.html#A_A In addition, if you need assistance completing the voluntary reporting form, the *Mandatory and Voluntary Problem Reporting for Medical Devices* guidelines can be found online at http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/man_vol_pro_rep_md_entire_e.html

Our lawyers have expertise in all areas of law relating to intellectual property, regulatory compliance, occurrence/risk management and investigation, litigation, products liability and look back programs. Please feel free to contact the authors for more information.

A B O U T T H E A U T H O R S :

Catharine Schiller and *Kathryn Frelick* are lawyers practicing in our Health Industry Practice Group and are responsible for the Legal Retainer Program. They focus on advocacy, regulatory and health policy issues.

Our National Health Industry Practice group is dedicated to providing comprehensive and integrated legal services to health industry clients. For more information about our group, visit our website at www.millerthomson.com or contact one of our regional contacts listed below.

REGIONAL CONTACTS

Toronto/Markham
Joshua Liswood
jliswood@millerthomson.ca

Kathryn Frelick
kfrelick@millerthomson.ca

Waterloo-Wellington
Gregory P. Hanmer
ghanmer@millerthomson.ca

Calgary
Bryan R. Ede
bede@millerthomson.ca

Edmonton
Brian J. Curial
bcurial@millerthomson.ca

Vancouver
David Martin
dmartin@millerthomson.ca

Miltom Consulting Inc.
Dr. Isser Dubinsky
idubinsky@miltomconsulting.com