

By Shirley Ha

patients will soon be shopping for their perfect costumes. Some will even want to accessorize their eyes with specialty contact lenses. The scary part of wearing decorative tinted contact lenses at Halloween should not be the eye damage it can leave behind.

Thanks to the collaborative • advocacy efforts of the Canadian Association of Optometrists (CAO), the Canadian Ophthalmological Society (COS), and the Opticians Association of Canada (OAC), the eye health of all Canadians is now protected by Bill C-313. The new legislation, which was effective July 16, 2017, ensures • that non-corrective cosmetic contact lenses are subject to the same regulations for eye health risks as corrective contact lenses. They are now classified as Class II devices under the Food and Drug Act and require oversight by a licensed eyecare professional (ECP).

The road to this enactment was certainly not an easy one. It took more than 15 years to make it a reality. Here's a summary of the process:

- In the mid-to-late 1990's, cosmetic contact lenses made their first appearance in the consumer market. Healthcare professionals warned Canadians about the increased risks and dangers associated with wearing unregulated cosmetic contact lenses, sold by retailers (beauty salons, dollar stores, pharmacies, gas stations, the Internet, etc.) without a prescription.
- In 2000, Health Canada issued a warning about cosmetic contact lenses and recommended that they be worn only under the supervision of an ECP.
- In 2003, Health Canada recommended that the federal government regulate the use of cosmetic contact lenses after the Dillon report¹ said that the level of health risk associated with cosmetic contact lenses is comparable

to, if not higher than, corrective contact lenses. The report also recommended risk management strategies that included screening for candidacy, proper fitting and training, education about use and hygiene, warning signs about when to seek medical attention should problems arise, and regular follow-up care.

- In 2007, Conservative MP Patricia Davidson (Sarnia – Lambton) introduced private member Motion No. 409, which moved that cosmetic contact lenses be regulated and classified as medical devices under the Food and Drug Act or the Hazardous Products Act.
- In March 2008, Motion No. 409 passed unanimously but died on the order paper when Parliament rose.
- In October 2011, Davidson introduced Bill C-313: An Act to Amend the Food and Drugs Act (non-corrective contact lenses), as a private member's bill before the House of Commons.

- In May 2012, Bill C-313 passed with 100 per cent support in the House of Commons.
- In November 2012, CAO presented and submitted An Act to classify non-corrective contact lenses as medical devices to the Senate Committee on Social Affairs, Science and Technology.
- In December 2012, Bill C-313 unanimously passed the Senate.
- On December 14, 2012, Bill C-313 received Royal Assent and became a statute
- On July 29, 2015, the federal Health Minister announced that Health Canada was going ahead with regulations to improve the safety standards for non-corrective cosmetic contact lenses to match those of corrective contact lenses. This became effective July 16, 2016, with a one-year extension for manufacturers, importers, distributors and retailers to apply for

- a Class II medical device sales license before they could sell these products.
- As of July 16, 2017, all non-corrective contact lenses sold in Canada are required to be licensed by Health Canada and are subject to the same licensing, manufacturing, labeling and instruction standards as corrective contact lenses.

This Halloween, despite the new regulations to decrease the risk of public harm from non-corrective contact lenses, many end-product distributors and many end users may still be unaware of the new legislation. Retailers may not know they are breaking the law and consumers may not understand the potentially harmful eye health consequences if they wear them without professional supervision.

Concerns remain high, particularly about less-than-reputable retail establishments that may try to sell last year's unsold and expired inventory. The penalties for illegal and dangerous distribution of

66 All non-corrective contact lenses sold in Canada are required to be licensed by Health Canada. 77

non-corrective contact lenses are unknown at the time of writing. Medical-device-related incidents can be reported by completing Health Canada's online Health Product Complaint Form at http://www.hc-sc.gc.ca/dhp-mps/ compli-conform/prob-report-rapport/ frm-0317-eng.php.

Have all the risks of wearing decorative contact lenses been eliminated? No, but, thanks to all the parties involved, Bill C-313 makes it possible for patients to be spooky-yet-safe at Halloween by making sure they have prescriptions, proper contact lens fittings and training by licensed ECPs.

The Dillon report was a health risk assessment of cosmetic contact lenses by Dillon Consulting Ltd., commissioned by Health Canada





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