October 1, 2018

Dr. John Patrick Stewart
Director General
Therapeutic Products Directorate
Health Canada
Address Locator: 3106B
Ottawa, ON K1A 0K9

Dear Dr. Stewart:

The Canadian Dental Association is the national voice for dentistry dedicated to the promotion of optimal oral health. Canada’s dentists are concerned about the potential health consequences to Canadians that result from offering direct to consumer oral healthcare and orthodontic services. This includes products from companies in the United States that have announced their expansion into Canada to market and sell dental aligners to patients.

Companies that market direct-to-consumer aligners are in fact promoting do-it-yourself and unsupervised orthodontic healthcare. This is concerning.

There are significant risks to Canadians when complex healthcare problems, including dental and orthodontic issues, are purported to be fixable through quick fix remedies that instead require direct care and treatment from a regulated healthcare professional.

These aligners, which we understand are classified as class II medical devices, are not passive appliances. They are active and designed to move teeth, change bites and have effects on the health and structure of the supporting soft and hard tissues.

Dental aligners are custom made, fabricated specifically for each individual, and must be treated as active dental appliances requiring the direct and ongoing supervision of a dentist. Firstly, the patient must be examined to determine if there is underlying oral disease that may cause harm during the treatment. Secondly, records must be gathered, housed and protected according to applicable privacy legislation, and not through unsupervised scan centres by unregulated personnel. Thirdly, informed consent requires a fulsome discussion regarding the treatment plan, including alternatives. Also, as you may be aware, the prescription or fitting of an orthodontic appliance is a restricted activity (or a controlled act) in all Canadian jurisdictions.
In order to better understand the health risks to Canadians, we request a review of the legality of the sale of aligners without appropriate oversight, directly to patients, and of potential avenues to ensure that patients are protected and receive necessary treatment under the ongoing supervision of a licensed dentist.

I thank you in advance for your assistance in the necessary investigation of the risk that unsupervised orthodontic treatment poses to Canadians.

Sincerely,

Dr. Michel Taillon
President