



## North America Legal and Regulatory Affairs

### Watchdog Update



#### Health Canada

Health Canada has no major announcements this month.

#### FDA

##### FDA Discusses First Approval of a CAR-T Immunotherapy

FDA's Drug Information Soundcast in Clinical Oncology from FDA's Oncology Center of Excellence discusses the recent approval of tisagenlecleucel, marketed as Kymriah.

[FDA D.I.S.C.O.: First FDA approval of a CAR T-cell immunotherapy](#) - mp3 file

[FDA D.I.S.C.O.: First FDA approval of a CAR T-cell immunotherapy](#) – Transcript

##### FDA research to improve technique for studying multipotent stromal cell morphology

Scientists at the U.S. Food and Drug Administration (FDA) demonstrated unexpected changes in the morphology (shape and size) of multipotent stromal cells (MSCs) when preparations of the cells interact with specific engineered culture systems. The finding is a step toward understanding how to accurately interpret studies that use such systems, called microfluidics platforms, so they can support the development of safe and effective medical products based on multipotent stromal cells.

[FDA research to improve technique for studying multipotent stromal cell morphology](#)